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Standards Applicable to Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities Under RCRA (Resource Conservation and Recovery Act), Subtitle C, Section 3004 Proposed Additions to Standards for Hazardous Waste Incineration (40 CFR 264.342 and 264.343)

(U.S.) Environmental Protection Agency
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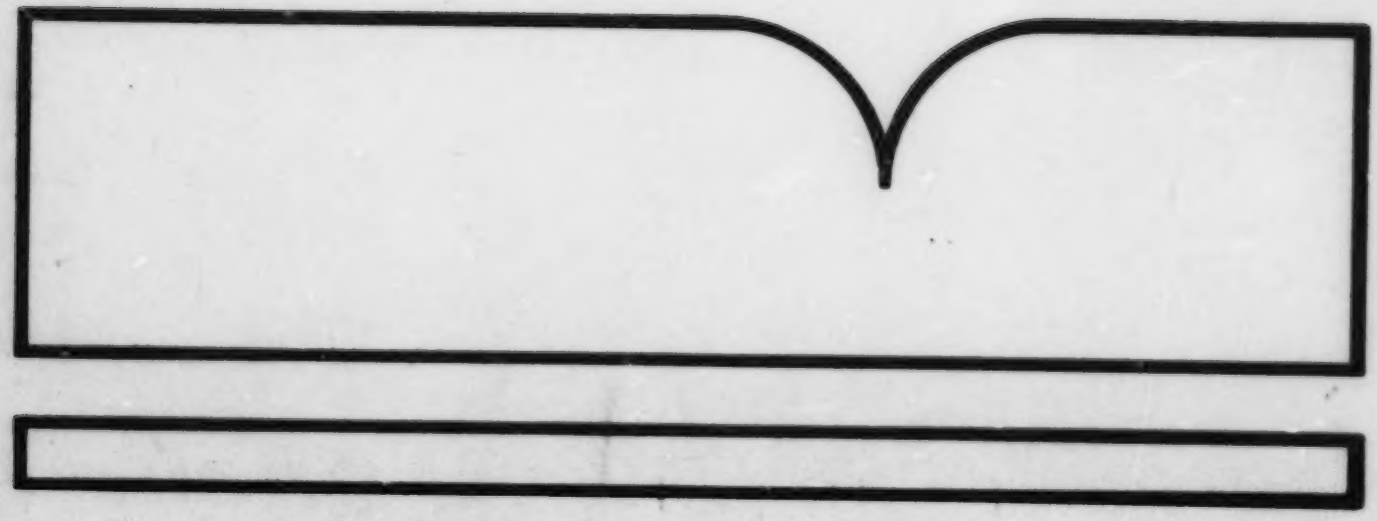

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This document is one of a series providing support for regulations issued by the US Environment Protection Agency (EPA) under Subtitle C of the Resource Conservation and Recovery Act (RCRA). The regulations represent the initial effort for nationwide control of hazardous waste from point of generation, through transportation, treatment, and storage, to point of ultimate disposal.

These are the major technical requirements which provide the basis for issuing permits under Part 122 of the regulations.

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BACKGROUND DOCUMENT

STANDARDS APPLICABLE TO OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES UNDER RCRA, SUBTITLE C, SECTION 3004

Proposed Additions to Standards For
Hazardous Waste Incineration
(40 CFR 264.342 and 264.343)

This document (ms. 1941.33) provides background information and support for EPA's hazardous waste regulations

U.S. ENVIRONMENTAL PROTECTION AGENCY
January 1981

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I. INTRODUCTION AND BACKGROUND

A. Content of the Background Document

This is one of a series of documents providing support and background information for regulations issued under Section 3004 of the Resource Conservation and Recovery Act of 1976. Each Background Document describes a regulation as originally proposed, summarizes and responds to comments received that relate to that original proposal, and indicates the Agency's rationale for final regulations.

On December 18, 1978, the Agency proposed standards for incineration of hazardous waste (43 FR, at 59008). As a result of that proposal, extensive comments were received. The Agency issued a limited set of Interim Status standards on May 19, 1980, and responded to some of those comments. Those standards, Part 265, Subpart O-Incinerators, were issued as interim final standards, subject to comment.

The Agency has now promulgated Interim Final Standards for incinerators. These are the major technical requirements which provide the basis for issuing permits under Part 122 of the regulations. These standards are discussed in another background document presenting the rationale for the final incineration standards, including response to the comments received on the proposed regulations.

The Phase II regulations rely on a basic performance standard (a destruction and removal efficiency at 99.99%) with facility specific operating conditions set to attain the performance

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standard. The basis for predicting compliance with the performance standard is trial burns. These burns define operating conditions associated with achievement of the performance standard. The operating conditions thus developed then become part of the permit and are the basis for continuous compliance monitoring. The engineering judgement of the permitting official is applied to define acceptable ranges of these operating conditions and in the composition of the wastes to which they may be applied. When sufficient alternative data are available to make these same determinations, the permitting official may waive the requirement for a trial burn.

This new proposal is designed to complement the Interim Final Standards. The proposed requirements allow permit writers to make variances (e.g., greater or less than 99.99% DRE) to the basic performance standards.

Specifically, this proposal adds the following to §264.343 Performance Standards:

(1) A procedure for a case-by-case variance from the minimum DRE of 99.99% when protection of human health requires a more stringent standard, or allows a less stringent standard.

(2) A provision which requires that the mass emission rate of hazardous by-products or products of incomplete combustion produced during combustion can be no more than 0.01% of the total mass feed rate of the principal organic hazardous constituents in the waste.

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(3) A case-by-case determination for limitations on emissions of toxic metals, hydrogen halides and elemental halogens.

The Agency believes that incineration of organic hazardous waste is the primary near-term alternative to land disposal. Incineration is capable of providing safe destruction of wastes. Large volumes of liquid organic wastes not suitable for land disposal can be reduced to safe gaseous emissions and smaller amounts of residues (ash, scrubber sludges, etc). Incineration can thus minimize or eliminate the long term impact on human health and the environment of many hazardous wastes.

B. RCRA Mandate for the Regulation

The Congress of the United States, in Section 3004 of Subtitle C of the Resource Conservation and Recovery Act (RCRA) of 1976 (PL 94-580), required that the Administrator of the U.S. Environmental Protection Agency:

> "...promulgate regulations establishing such performance standards, applicable to owners and operators of facilities for the treatment, storage, or disposal of hazardous waste identified or listed under this Subtitle, as may be necessary to protect human health and the environment. Such standards shall include, but need not be limited to, requirements respecting -...
>
> (3) treatment, storage, or disposal of all such wastes received by the facility pursuant to such operating methods, techniques, and practices as may be satisfactory to the Administrator;
>
> (4) the location, design, and construction of such hazardous waste treatment, disposal, or storage facililties;"
> (emphasis added).

The term "treatment" is defined in Section 1004(34) of the Act to mean:

"...any method, technique, or process, including neutralization, designed to change the physical, chemical, or biological character or composition of any hazardous waste so as to neutralize such waste or so as to render such waste non-hazardous, safer for transport, amenable for storage, or reduced in volume..."

One objective of incinerating hazardous waste is normally to change the physical form or chemical composition of the waste so as to render it non-hazardous. Incineration may also render the waste "safer for transport, amenable for recovery, amenable for storage, or reduced in volume." Therefore, incineration is a treatment process within the meaning of the Act, and the Agency is mandated to produce operating, location, design, and construction regulations for the incineration of hazardous waste adequate to protect human health and the environment.

C. Key Definitions

The definitions given in Part 260 of the Regulations promulgated on May 19, 1980 (45 FR at 33066) should aid the reader in understanding this document. Some of those definitions are provided here for the readers' convenience. Changes from the definitions proposed on December 18. 1978 (43 FR at 58946) are discussed if they are relevant to the incineration standards.

1. "Disposal" means the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air, or discharged into any waters, including groundwater.

2. "Disposal Facility" means a facility or part of a facility at which hazardous waste is intentionally placed into or on any land or water, and at which waste will remain after closure.

3. "Facility" mens all contiguous land, and structures, other appurtenances and improvements on the land, used for treating, storing, or disposing of hazardous waste. A facility may consist of several treatment, storage, or disposal operational units (e.g., one or more landfills, surface impoundments, or combinations of them).

4. "Fugitive Emissions" means air contaminant emissions from non-point emission sources, or other than those from stacks, ducts, or vents.

5. "Hazardous Waste" means hazardous waste as defined in §261.3 of the Regulations promulgated On May 19, 1980 (45 FR at 33119).

6. "Hazardous Combustion By-Products" (products of incomplete combustion) are hazardous organic constituents formed in an incinerator from incomplete combustion of POHC's to which the emission rate limit in §264.341(b) applies. Hazardous combustion by-products will be designated by the Regional Administrator:

   (1) during the conduct of a trial burn (or review of alternate data) performed under §264.344, and based on the intermediate results of the trial burn.

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(2) utilizing the criteria in paragraph (c) of this Section.

7. "Incinerator" means an enclosed device using controlled flame combustion, the primary purpose of which is to thermally break down hazardous waste. Examples of incinerators are rotary kiln, fluidized bed, and liquid injection incinerators.

8. "Principal Organic Hazardous Constituents (POHC's)" are the one or more organic constituents in a waste to be incinerated to which the Destruction and Removal Efficiency (DRE) standard in §264.341(a) applies. POHC's will be designated by the Regional Administrator:

(1) prior to a trial burn (defined under §264.344)

(2) based on the results of the waste analysis performed under §264.345, and

(3) utilizing the criteria in paragraph (c) of this Section.

9. "Treatment" means any method, technique, or process, including neutralization, designed to change the physical, chemical, or biological character or composition of any hazardous waste so as to neutralize such waste or so as to render such waste non-hazardous, safer for transport, amenable for recovery, amenable for storage, or reduced in volume.

10. "Trial burn" means an experimental burn of a hazardous waste in an incinerator in order to evaluate the

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capability of an incinerator of that design to achieve a specified performance (destruction and removal efficiency) and to establish the operating conditions (temperature, air flow, etc.) necessary to achieve that performance for the incinerator permit.

II. Need for Additions to the Final Incinerator Performance Standards

EPA has recognized that incineration of hazardous wastes is one of the primary waste management techniques which is preferable to land disposal. In preparing the final standards, the Agency determined that the following performance standards were state-of-the-art and were fully supportable based on existing data:

1. a minimum Destruction and Removal Efficiency (DRE) of 99.99% based on one or more Principal Organic Hazardous Constituents (POHC's)
2. a minimum removal efficiency of 99% for hydrogen choride gas when chlorine was present in the feed in excess of 0.5%, and
3. a maximum particulate emission standard of 180 milligrams per dry standard cubic meter, corrected to 12% carbon dioxide in the exhaust gas.

However, as these performance standards were being developed and finalized, the Agency became increasingly aware of the limitations of these standards. Specifically, major limitations of these standards are as follows:

1. The DRE of 99.99% is a percentage removal or destruction standard and does not provide for regulation of the absolute quantities of POHC's which can be emitted. By basing the exit emissions to the environment on a percentage of the rate of waste being fed to the incinerator, a large incinerator capable of a high

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feed rate would be allowed to emit larger quantities of unburned POHC's. A small incinerator unit on the other hand, which could handle only a small waste feed would be restricted to a smaller quantity of POHC emitted. Thus the DRE value of 99.99% is based on a minimum technology capability and not on the impact of waste emissions on the environment and human health. Also comments received on the 1978 proposed regulations expressed a need to develop standards which reflect the degree of hazard that wastes represent. Wastes which represent a low level of hazard to human health and the environment should not have as stringent regulatory requirements as highly dangerous wastes.

2. The DRE of 99.99% does not account for Hazardous Combustion by-products (HCBP) which are known to be formed in the combustion of many waste substances. Documentation on the formation and emissions of HCBP's is increasing at a rapid rate through ongoing laboratory test work and field sampling (5,24). HCBP's may in some situations be more hazardous to the environment and human health than the wastes being fed to incinerators (POHC's). The Interim Final Standards provide no regulatory control over HCBP's.
3. Both the DRE of 99.99% and the particulate standard of 180 mg/DSCM do not regulate the emissions of inorganic hazardous constituents such as heavy metals, hydrogen halides and elemental halogens other than HCl.

The DRE has been documented only for organic compounds which can be reduced by oxidation to CO_2, H_2O and other relatively harmless simple compounds. Metals cannot be destroyed by oxidation or other chemical means and can be emitted in a number of forms such as:

- solids in the incinerator ash
- vapors in the exhaust gases
- particulates in the exhaust gases
- solid or liquid phase in the scrubber effluent.

In these situations the DRE for organic compounds is of no value and the particulate standard of 180 mg/DSCM may allow emissions of sufficient quantities of metals as solids to endanger human health and the environment. The particulate standard is of no value in the case of emissions of vaporized metals.

4. The control of emissions of elemental halogens and hydrogen halides other than HCl, is also lacking in the Interim Final performance standards. HCl is controlled with the 99% removal requirement but EPA was unable to find data on emission control system performance for the other halogens and hydrogen halides. Thus no technology based removal standard was established.

EPA in identifying these limitations of the final performance standards for incinerators has developed a proposal to be added to the performance standards in §264.343 which will accomplish the following:

- Provide for a variance to the DRE of 99.99% which directly links the allowable emission rates of POHCs and HCBP's to anticipated human health impacts
- Place a bench-mark limit on HCBP's similar to the DRE of 99.99%
- Allow emission limits to be established for metals, elemental halogens, and hydrogen halides based on their impact on human health.

Section IV of this Background Document explains the rationale for this proposal and provides examples of how they would be applied.

III. Role of Risk Assessment in Regulating Incineration

Many of the comments on the proposed incinerator regulations (FR December 18, 1978) objected to the proposal on two major grounds: 1) the universally applicable specific design and operating requirements were too inflexible and not justifiable and 2) the performance requirements did not allow variances to reflect case-by-case situations. EPA concluded that these comments had merit. The differences in wastes and incinerator designs argue that operating requirements can not be effectively established on a national basis and that performance standards should be tailored to case-by-case situations to better ensure protection of human health and also avoid overly stringent requirements. The Interim Final standards (IF) reflect this approach in that operating and design standards were dropped and performance standards promulgated. However, the IF standards do not provide for a case-by-case variance to the basic performance standard. The question of how a variance to the performance standards would be determined is a major question.

The use of a risk assessment approach for emissions from incinerators has been adopted by EPA as the best available methodology to link incinerator performance requirements to human health impacts. This will be based on an evaluation of risk to human health posed by the emissions from the incinerator stack. The proposed standard defines the basic factors involved in this assessment, including stack emissions, dispersion modeling, consequent human exposure, and the health effects of the exposure. It does not define a specific methodoloy.

If a risk assessment indicates that a more restrictive emission limit is needed to protect human health, the permit writer may lower the mass emission rate either by requiring a higher destruction and removal efficiency or specifying a lower waste feed rate or both. In a like manner, the permit writer may approve a lower destruction and removal efficiency (or higher feed rate) if a risk assessment indicates that no significant impact on human health will result.

The factors of stack emission rates and dispersion models can be addressed utilizing data from engineering calculations, the trial burn (stack emissions), and existing air dispersion models developed under the Clean Air Act. The determination of health risk can be based on available EPA "dose response models" for a certain number of carcinogens. For other substances, the estimation of health effects will be less direct, and will depend on scientific judgments based on the best health effects data available, or using benchmarks of acceptable exposure such as threshold limit values (TLV's). The methodology for conducting risk assessments is described more fully in Section IV of this Background Document.

The Agency recognizes that in many instances it may not be possible to conduct an acceptable risk assessment. When a risk assessment is not possible or is not requested by the applicant or required by the permit writer, the performance standard of 99.99 percent DRE will be the basis for permitting. EPA expects that over time, data will be developed to expand risk assessment capabilities.

The integration of the variance procedure into the permitting process could occur in several ways. It could be carried out prior to the trial burn, after the trial burn but before issuance of a draft permit for public comment, or as a consequence of public comment.

A risk assessment to support a variance could be required by the permit writer or requested by the applicant prior to conduct of a trial burn. This would be advantageous in that the applicant would know prior to the trial burn whether he would need to demonstrate a performance other than 99.99% DRE. Thus, he may be able to avoid having to repeat a trial burn, although the POHC's and hazardous combustion by-products will not be finally determined until the trial burn is complete. In most instances, the trial POHC's, designated by the permit writer from waste analysis data included with the trial burn plan, will also be the final POHC's. Hazardous combustion by-products present a more difficult problem. While a prediction may be made, the trial burn may indicate different or additional by-products than those predicted. Should this occur, a risk assessment for those new hazardous by-products would have to be performed after the trial burn.

If the applicant were requesting that a risk assessment for a variance be performance, this request would be included in a "variance assessment plan" submitted as a part of the trial burn plan. It would include a description of the proposed methodology to be used in the assessment. In reviewing the variance assessment plan, the permit writer would accept or, require modification

of, the risk assessment methodology, and would designate the trial POHC's and trial hazardous combustion by-products to be included in the risk assessment. The risk assessment would be performed and the results submitted to the permit writer to complete the trial burn plan.

In cases where the applicant does not request a variance assessment, but instead it is required by the permit writer upon review of the trial burn plan, the applicant would be requested to amend the plan with a methodology for the risk assessment. Then the process would proceed as described above. In either case, the performance of the risk assessment prior to conduct of a trial burn, would add a step to the trial burn application process. That step would require that a new part be added to the trial burn plan. The permit writer would approve that part of the plan, and the applicant would complete the assessment and submit it to the permit writer to complete the trial burn plan. In addition, the applicant or permit writer might decide to provide an opportunity for public comment on the results of the risk assessment and the variances determined by the permit writer prior to conduct of the trial burn.

In cases where a waiver of the trial burn is requested in Part B of the permit application, the same procedure would be followed regarding a risk assessment variance. It would then mean that Part B would not be considered final until a determination of need for, and, where appropriate, completion of, a risk assessment were made.

The second method, for including a risk assessment into the permitting process is to conduct the assessment following the trial burn. A probable basis for requiring a risk assessment at this time would be that the data from the trial burn revealed hazardous by-products which were not predicted. A risk assessment at this juncture could be requested by the applicant in his submittal of trial burn results in Part B of the permit application, required by the permit writer upon review of those results prior to issuance of a draft permit, or requested by the public as a part of their review of the permit application or draft permit. Should this occur, the applicant would be requested to submit a methodology for the risk assessment, and upon approval, conduct the assessment and submit the results to the permit writer, esentially as a modification of the permit. If review of the results causes the permit writer to exercise the variance and alter the performance standard, a repeat of the trial burn may be necessitated. If so a new trial burn plan would be required, in essence returning to the beginning of the permit application process.

In a similar manner limitations on the emission of toxic metals, elemental halogens and hydrogen halides can be established. A preliminary trial burn plan would include a proposed methodology for assessing acceptable risks associated with metals and non-organic halogens (except HCl), when applicable. Upon approval, this assessment would be completed and the data submitted to the permit writer to complete the trial burn plan. Based on these data the permit writer would establish emission

limits on metals and non-organic halogens to be achieved in the trial burn. In this instance, as well as in the variance procedure, the permit writer or applicant may provide opportunity for public comment on the results of the risk assessment and selected performance standards, prior to conduct of the trial burn. Thus EPA will determine emission limitations of these inorganic materials in a manner identical to the variance procedure for the DRE.

IV. Rationale for the Proposed Regulation

A. Emission Limits for Hazardous Combustion By-Products

Questions raised by commenters to the proposed reuglations published December 18, 1978, led the Agency to recognize that in additon to defining hazardous constituents in the waste burned in an incinerator, it is important to define hazardous combustion by-products formed during incineration. Many hazardous wastes may simply break down and recombine in an incinerator into other forms of hazardous organic ocmpounds if combustion is not complete. Thus, even though the principal organic hazardous constituents (POHC's) in the waste feed may be destroyed in accordance with the destruction and removal efficiency standard, the stack gases may contain other hazardous constituents formed during incineration.

The Agency has continued to collect evidence that hazardous combustion by-products of incineration are a concern. EPA has sponsored laboratory studies at the University of Dayton of the thermal decomposition of complex organic halogen compounds which illustrate the potential for formation of these by-products.(24) Some of the experimental results are shown in figures 1 through 4 and Table 1.

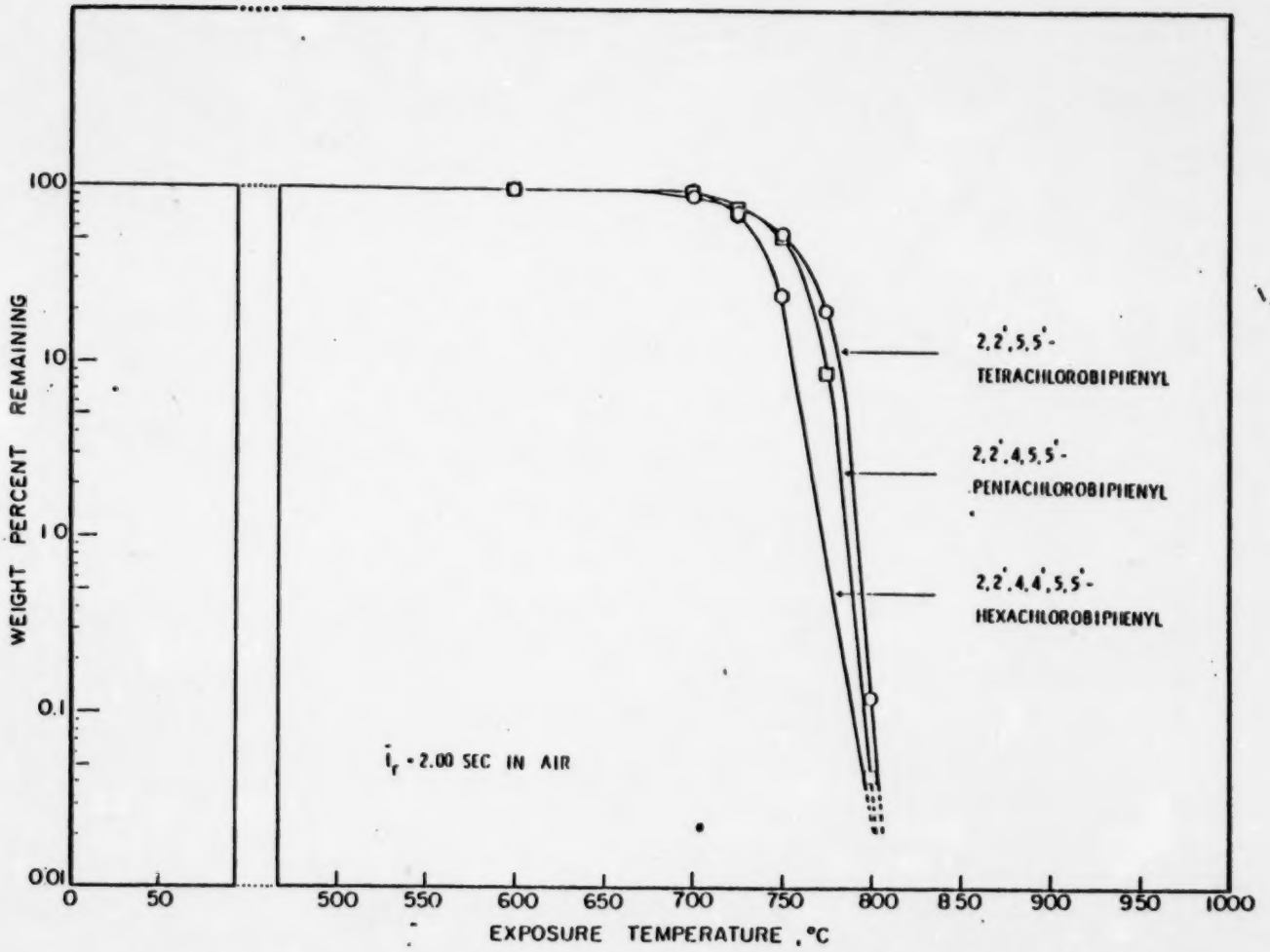
Thermal decomposition profiles were obtained for the tetra-, penta-, and hexachlorobiphenyl isomers of PCB, in a flowing air environment at two (2) seconds residence time, and at the exposure temperatures shown in Figure 1. There was little difference in thermal stability noted among the three isomers, except the hexa-form appears to break more sharply between 650° and 700°C.

Figure 2 illustrates the production of by-product trichlorodibenzofuran from tetrachlorobiphenyl at temperatures of 650°C up to approximately 750°C. Figure 3 illustrates the production of four by-product compounds from the thermal decomposition of 2, 2', 4, 5, 5' -pentachlorobiphenyl in a nitrogen atmosphere. Figure 4 similarly illustrates the production of several polychlorinated benzene compounds from 2, 2', 4, 4', 5, 5' -hexachlorobiphenyl. Figures 2-4 clearly demonstrate the generation of by-product compounds at temperature levels commonly used in incinerators.

Table I shows results from the University of Dayton work with three selected isomers of PCB's (Polychlorinated biphenyls). It is noted that a variety of benzenes, biphenyls, dibenzofurans and other chlorinated ocmpounds were detected as decomposition by-products.

In order to protect human health and the environment, it is essential that a performance standard be applied to these substances as well. In some cases the combustion by-products produced may be more toxic than the unburned POHC's.(5) This proposed amendment to the final regulation requires that the mass emission rate of hazardous combustion by-products must not exceed 0.01 percent of the total mass feed rate of POHC's fed to the incinerator. The rationale for this standard is as follows: if the combustion by-product were introduced to an incinerator as a principal organic hazardous constituent (POHC) in the feed, then it would be subject to the DRE standard of 99.99%. Thus the combustion by-products should be controlled to the same level as the POHC's.

FIGURE 1



Source: Duvall, D. S.; Letter on Research Results Utilizing the TDAS; University of Dayton; to R. A. Carnes, October 1979.

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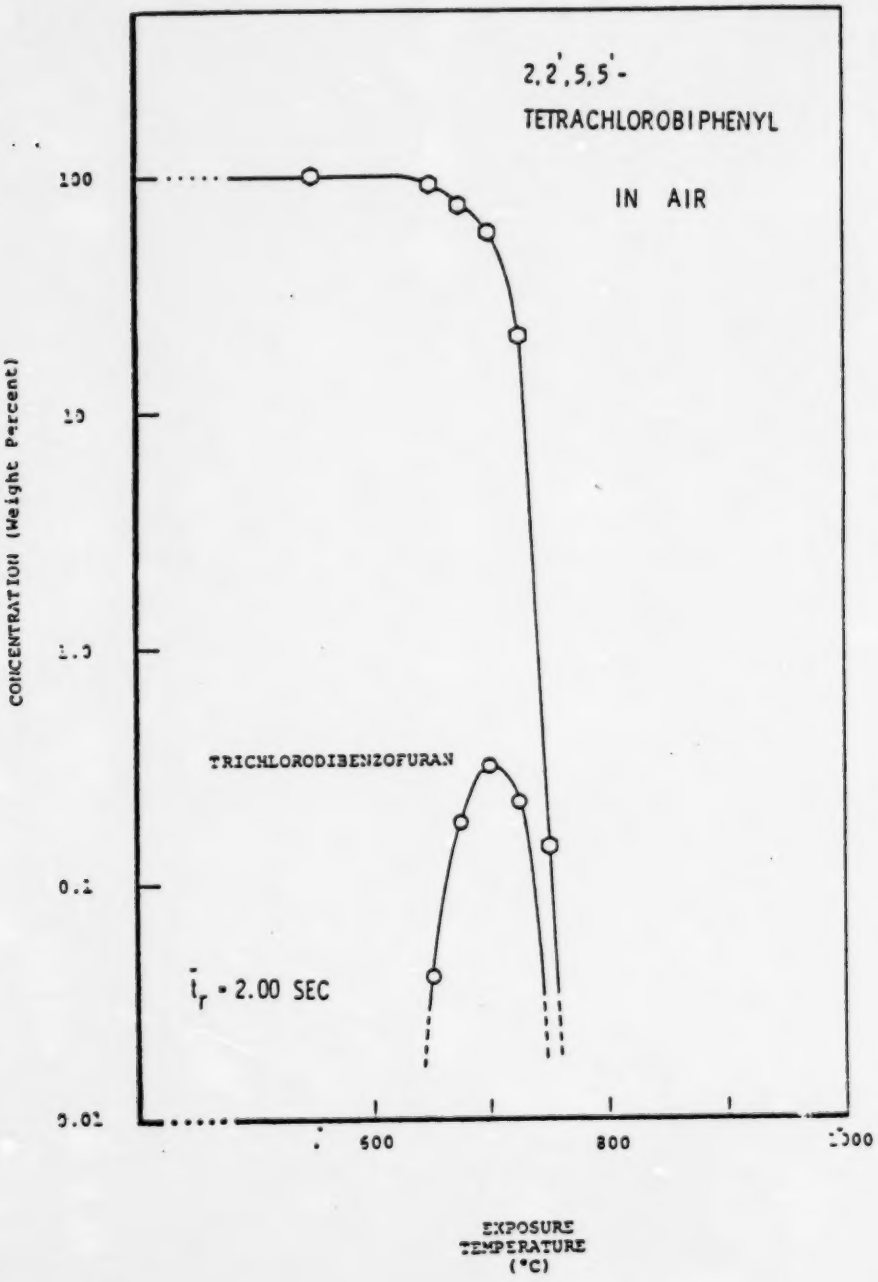

Source: Duvall, S. D.; Letter on Research Results Utilizing the TDAS; University of Dayton; to R. A. Carnes, October 1979.

FIGURE 2

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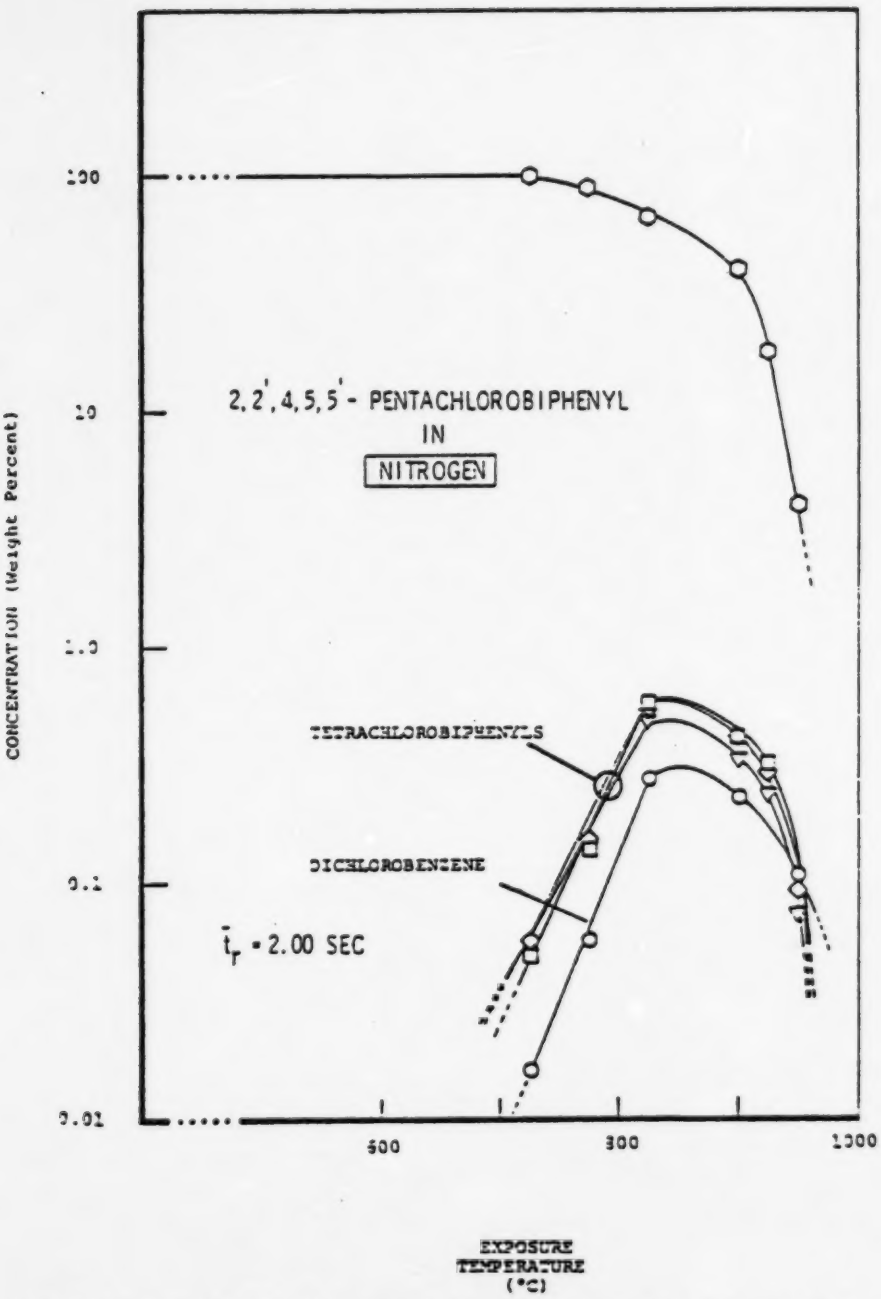
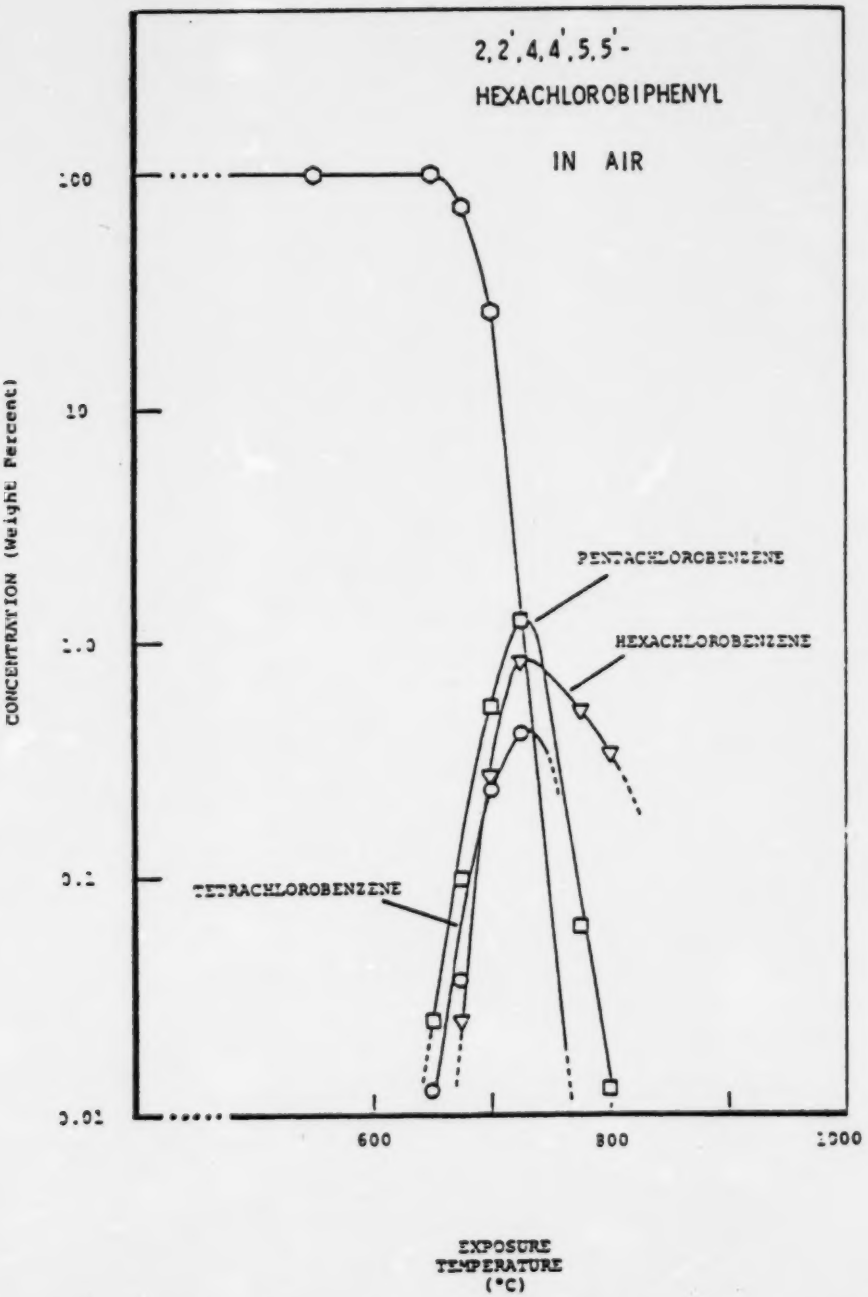


Source: Duvall, D. S.; Letter on Research Results Utilizing the TDAS; University of Dayton; to R. A. Carnes, October 1979.

FIGURE 3



Source: Duvall, D. S.; Letter on Research Results Utilizing the TDAS; University of Dayton; to R. A. Carnes, October 1979.

FIGURE 4

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TABLE I

ORGANIC COMPOUNDS IDENTIFIED FROM THE DECOMPOSITION OF SELECTED PCB ISOMERS IN FLOWING AIR AT 725°C FOR A RESIDENCE TIME OF 2 SECONDS

Compounds	Isomers 2,2',5,5'	2,2',4,5,5'	2,2',4,4',5,5'
trichlorobenzene	+	+	-
biphenyl	+	-	-
tetrachlorobenzene	+	2 isomers	+
monochlorobiphenyl	+	+	-
chlorinated compound MW204+	+	-	-
dichlorobiphenyl	+	+	-
pentachlorobenzene	-	+	+
chlorinated compound MW230+	2 isomers	-	-
trichlorobiphenyl	2 isomers	+	+
dichlorodibenzofuran	+	-	-
tetrachlorobiphenyl	2 isomers	+	-
pentachlorobiphenyl	2 isomers	+	-
trichlorodibenzofuran	+	+	-
hexachlorobenzene	-	+	+
chlorinated compound MW264+	-	3 isomers	-
tetrachlorodibenzofuran	-	2 isomers	-
hexachlorobiphenyl	-	+	+
heptachlorobiphenyl	-	-	+
pentachlorodibenzofuran	-	-	+
chlorinated compound MW288+	-	-	+

+ = tentative identification

- = not found

Source: Duvall, D. S.; Letter on Research Results Utilizing the TDAS; University of Dayton; to R. A. Carnes, October 1979.

In addition, any combustion by-products detected will be subject to an assessment of their impact on human health and the environment in the same manner as the POHC's. The assessment method is explained in detail in Section IV-B.

Hazardous combustion by-products which are subject to the proposed standard will be designated by the permit-writer. This designation will either take place during the course of the trial burn based on the analysis of the incinerator emissions, or the owner or operator may present data in the trial burn plan from laboratory, pilot or full scale burns where hazardous combustion by-products have been identified. In cases where a trial burn waiver is requested, this predictive approach is the only means of identifying combustion by-products. EPA has research facilities which may be used to assist owners and operators in this area. These facilities are discussed in more detail in the Background Document on Subpart O - Interim Final Standards.

Proposed Regulatory Language

§264.342 Designation of principal organic hazardous constituents and hazardous combustion by-products.

(a) Principal organic hazardous consituents (POHCs) and hazardous combustion by-products must be treated to the extent required by the performance standards specified in §264.343.

(b)(i) For each waste feed to be burned, one or more POHC's and hazardous combustion by-products will be specified from among those constituents listed in Part 261, Appendix VIII of this Chapter. This specification will be based on the degree of difficulty of

incineration of the organic constituents of the waste feed and its combustion by-products, their concentration or mass, considering the results of waste analyses and trial burns or alternative data submitted with Part B of the facility's permit application. Organic constituents or by-products which represent the greatest degree of difficulty of incineration will be those most likely to be designated as POHCs or hazardous combustion by-products. Constituents are more likely to be designated as POHCs or hazardous combustion by-products if they are present in large quantities or concentrations.

(ii) Trial POHCs will be designated for performance of trial burns in accordance with the procedure specified in §122.27(b) for obtaining trial burn permits. Trial hazardous combustion by-products may be designated under the same procedures.

* * * * *

§264.343 Performance standards.

* * * * *

(d) Incinerators burning hazardous waste must destroy hazardous combustion by-products designated under §264.342 so that the total mass emission rate of these by-products emitted from the stack is no more than .01% of the total mass feed rate of POHCs fed into the incinerator.

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B. Variance to the Destruction and Removal Efficiency.

In the December 18, 1978 proposed standards for incinerators no variance procedure to the destruction efficiency was proposed. Among the many comments received on the 1978 proposal were suggestions that a variance procedure should be established to account for the differences in the degree of hazard of waste emissions and to reflect specific site-by-site differences.

EPA agrees that a variance procedure is desirable and sometimes necessary, in order to ensure adequate protection of public health. The destruction and removal efficiency of 99.99% minimum, although the most feasible and defendable state-of-the-art standard, suffers from a significant short coming. The approach is a percent removal approach, and therefore, allows varying amounts of actual emissions (mass per unit time) depending on the composition of the waste (concentration of hazardous constituents) and the rate of feed of the waste. The 99% removal requirement for hydrogen chloride suffers from the same shortcomings.

For example, if 10,000 lbs of a waste were burned, one pound of a toxic component would be discharged assuming a 99.99% DRE. In the case of highly toxic components such as some of the dioxin isomers, such a quantity of mass emissions may be unacceptable, depending on the mass feed rate of the dioxin containing waste. The "pure" DRE approach in the example would permit the owner or operator to discharge one pound over an unspecified period of time. A large incinerator could be discharging large quantities of hazardous materials over a period extending from minutes to years while remaining in compliance with the 99.99% DRE.

1. Variance Based on Risk Assessment

In order to meet the RCRA mandate of protection of human health and the environment, a procedure is provided in the proposed regulation for a variance to the DRE based on an assessment of risk to human health. No particular methodology is provided in these proposed regulations for performing the risk assessment. However, the Agency is providing below a sample approach to risk assessment which it believes will satisfy the requirements of the proposal. The reader is cautioned that the sample procedure presented is but one example of how a risk assessment would be conducted.

The conceptual approach to risk assessment which is presented as an example in this background discussion is a determination of individual incremental risk at the point of greatest ground level concentration of emissions from the incinerator. The actual presence of individuals at this point, or the number of individuals is not a factor in the determination. This approach is conservative in protection of health.

This is a relatively simplified approach to risk assessment. It assumes, in essence, that any individual is exposed to the greatest ambient concentration of hazardous constituents, regardless of where that may be. It avoids the difficult and often disputed estimates of actual total population exposure to different concentrations. A total population exposure analysis could be performed as a part of risk analysis if desired. The consideration of population likely to be exposed can be considered in

making a judgement of an acceptable risk. The proposed regulation does not suggest an acceptable risk value.

The cancer induction model is based on life time average exposure. Thus, short term variations in concentrations need not be determined for cancer induction. There is a strong history to support the regulatory and technical basis for the carcingen risk assessment approach (6,7,8,9,10). The reader should analyze the referenced material for more details.

The overall approach to conducting a carcinogen-based risk assessment is as follows:

- Based on data from the trial burn (or alternate data) the mass emission rate of POHC's, hazardous combustion by-products, and toxic metals from the incinerator stack is determined or calculated.
- Appropriate air dispersion models are applied to these emissions to predict the ground level ambient concentrations.
- Using the greatest level of ambient concentration, a cancer risk assessment model (dose response model) is applied to determine the risk to an individual of developing cancer.
- The Regional Administrator (and the public through hearings) makes a judgement as to whether this level of risk is acceptable. If it is not, then an acceptable level of risk is determined. Based on this risk, the calculations are made in reverse to determine the maximum permissible level of stack emissions.
- In order to achieve this level of stack emissions, the Regional Administrator either can impose a more stringent level of destruction and removal efficiency and/or can limit the mass feed rate to the incinerator.

A risk assessment may not be needed in every case. The impetus for a risk assessment can come either from the Regional Administrator, the permit applicant, or the public. The burden

of conducting the risk assessment is on the permit applicant in all cases. Further, any risk assessments for the purpose of lowering the DRE (making it less stringent) must come from the permit applicant. When a risk assessment requested by the Regional Administrator indicates that a 99.99% DRE provides an acceptable level of risk, the DRE will remain at 99.99% unless there is a specific request from the permit applicant.

2. Limitations of the Risk Assessment Approach

There are a number of limitations to the application of the risk assessment variance approach. They are discussed in the following paragraphs:

(i) The capability to conduct a quantitative risk assessment at the present time is most clearly defined for certain carcinogenic substances. Currently, actual dose response data for inhalation of carcinogens exist for 21 substances (Table II). These have been evaluated by the EPA Cancer Assessment Group (CAG) for carcinogenic potency for inhalation. The data exist in the technical literature to develop dose response curves for virtually all of the approximately 150 known and suspected carcinogens. The EPA Cancer Assessment Group (CAG) expects to develop dose response data for all of the compounds for which adequate data exist.

(ii) In doing an assessment of risk using cancer data, the user should be aware that the development of cancer data is a new science and is subject to degrees of uncertainties and even disagreement among those working in the field. Specifically:

Table II

THE CARCINOGENIC ASSESSMENT GROUP'S PRELIMINARY CARCINOGENIC POTENCY ESTIMATES ON COMPOUNDS INCLUDED IN AIR PROGRAM

Compound	Potency Slope $(ug/m^3)^{-1}$
Acrylonitrile	8.50×10^{-5}
Allyl Chloride	2.66×10^{-6}
Arsenic	3.00×10^{-3}
Benzene	7.40×10^{-6}
Beryllium	2.70×10^{-1}
Cadmium	1.90×10^{-3}
Diethyl-Nitrosamine (DEN)	7.18×10^{-2}
Dimethyl-Nitrosamine (DMN)	4.35×10^{-3}
Ethylene Dibromide	5.90×10^{-4}
Ethylene Dichloride	1.20×10^{-5}
Ethylene Oxide	1.20×10^{-4}
Formaldehyde	6.53×10^{-5}
Manganese	4.0×10^{-4}
Nickel	1.80×10^{-3}
N-nitroso-N-ethylurea (NEU)	6.66×10^{-3}
N-nitroso-N-methylurea (NMU)	0.67
Perchloroethylene	7.60×10^{-6}
TCDD	121.428
Trichloroethylene	8.80×10^{-7}
Vinyl Chloride	1.43×10^{-3}
Vinylidene Chloride	5.93×10^{-5}

1. The degree of certainty for carcinogenic effects is different for each compound.
2. The value of the potency (B_H) is different for each element or compound and directly reflects the degree of carcinogenicity.
3. The experimental or human exposure data has been obtained from different exposure routes, ingestion, inhalation, and skin absorption. Methods of converting exposure data from one exposure route to another have been developed using reasonable assumptions. However, these transformations introduce additional uncertainities into exposure data. It is important to note that the potency (B_H) slopes for the same element or compound may be different for each of the exposure routes.

Since the field is in a rapid state of development anyone applying cancer induction data to assess environmental and health impacts should insure that the data is current.

The cautions above should not be taken as an excuse to avoid proceeding with a risk assessment based on the cancer effects of chemicals, as these effects are very real.

(iii) A variance analysis may also be conducted for substances which do not manifest carcinogenic effects. In this case the threshold assumption may be used in deriving a criterion. This assumption is based on the premise that a physiological reserve capacity exists within the organism which is thought to be depleted before clinical disease ensues. Alternatively, it may be assumed

that the rate of damage will be insignificant over the life span of the organism. The Threshold Limit Value (TLV) for worker exposure to chemical substances published by the American Conference for Government Industrial Hygienists (ACGIH) is an example of a threshold approach for non-carcinogens. The TLV could be modified by a "safety factor" to derive an ambient exposure concentration value. There are two major drawbacks to the use of the TLV. These are:

1. The general population contains subgroups more susceptible than workers, e.g., the old, young children, and people with illnesses.
2. Workers are exposed typically for eight hours a day. General populations are exposed on a continuous 24-hour basis.

Assessments using the TLV approach therefore will require judgment on the part of the permitting official. The advantages of using OSHA type standards are:

(1) they apply to a wide variety of toxic substances,
(2) the TLVs are largely inhalation based,
(3) TLVs are continually updated [11],
(4) TLVs are derived directly from experimental human and animal studies,
(5) they are already a part of the law,
(6) a methodology exists for handling mixtures of compounds for which TLVs exist [26]. This methodology is for the workplace and would be modified for application to ambient usage.

The history of each TLV should be examined to assess the extent to which it has assured worker safety in past application.

An alternative is to use the multi Media Environmental Goals (MEGs) which have been produced by EPA for use in performing environmental assessments. Some 650 compounds have been analyzed and ambient concentrations for most of them have been derived for air, land and water[25].

The carcinogen-based risk assessment approach is based on a non-threshold concept of disease induction. The threshold concept considers a level of environmental contamination below which there is no adverse effect. The TLV is based on this concept:

> "Threshold Limit Values refer to airborne concentrations of substances and represent conditions under which it is believes that nearly all workers may be repeatedly exposed day after day without adverse effect."[25]

A concept for criteria setting, including the TLV, has been proposed by EPA[25].

(iv) Another factor which complicates risk assessment is the determination of an acceptable risk. This determination is as much a political/social decision as a technical one. For many of the risk assessments the estimated risk will be in a range of fairly clear acceptability or unacceptability. However, for those cases in the "gray area", the judgment of the permitting official and the reaction of the public in the public hearing process will impact the determination of acceptability.

3. Use of Atmospheric Dispersion Modeling for Incinerators Emitting Hazardous Wastes

Dispersion modeling will be used in this application to estimate the maximum allowable emissions of each hazardous substance such that the incinerator impact does not exceed any of the specified ambient air concentrations related to a specified risk level. That is, each incinerator is modeled to determine emission limits that are specific to that incinerator. In cases where several incinerators emit hazardous substances in the same area, the incinerators should be modeled simultaneously in order to account for the combined impact of these sources.

The purpose of this section is to provide an overrview of the role of modeling in reviewing permit applications for hazardous wastes incinerators, indicate the extent to which procedures are available to do that modeling, and outline some of the data requirements for the models. This discussion points out that procedures for dispersion modeling are available, are supplemented with guidance, and are applicable to hazardous waste incinerators. Persons involved in a modeling analysis pertaining to the incineration of hazardous wastes should be thoroughly familiar with both the modeling guidelines and the user's manual of the model(s) selected. In addition, those conducting the analysis should have sufficient expertise in air quality modeling to make the judgments required in the modeling exercise.

Dispersion modeling will be carried out using the recommendations of the EPA Guideline on Air Quality Models[12] The guideline recommends specific models for various situations. The guideline

also makes recommendations concerning the source and meteorological data to be used in these models. The guideline is expected to be updated intermittently. In all cases the most recent version of the guideline should be used.

The Guideline on Air Quality Models discusses both screening techniques and refined modeling techniques[12].* The screening techniques are simple calculations and tend to be based on conservative assumptions. Thus, if screening shows that an allowable concentration is not exceeded, then a more refined technique will give the same conclusion and a more refined analysis is not required. If on the other hand, a screening results in a concentration in excess of the allowable concentration, it is desirable to use a more refined technique for estimating atmospheric concentrations of hazardous substances. The Guideline has been published in the Federal Register by EPA and has been tested in the courts to some extent [12,13,14].

Model Selection

Three factors are most significant in selecting an air quality model: (1) The nature of the pollutant (i.e., inert vs. chemically reactive); (2) the nature of the emission source or sources (e.g., point source); and (3) averaging time (i.e., the

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* Some proposed revisions to the Guidelines on Air Quality Models are discussed in Regional Workshops on Air Quality Modeling: A Summary Report (Draft). These proposals principally reflect additional refined models which might be recommended and greater refinement of guidance on various modeling issues. However, until revised guidelines are issued (expected in Spring 1981), the 1978 guideline should be followed.

time period over which concentrations are to be averaged). Other considerations are sometimes important; for example, the occurrence of an unusual meteorological phenomenon, terrain feature or source characteristic will often require the use of a specialized model. Nevertheless, these factors are useful in narrowing the choice of models.

Hazardous pollutants should generally be considered chemically unreactive. This is a conservative assumption in that the maximum concentration at the point of exposure is derived using this approach. Even in cases where the pollutant does decompose in the atmosphere, it is appropriate to use an inert pollutant model in conjunction with using a half-life approach to simulate chemical disappearance of the pollutant. Chemical removal may be considered only if the applicant can demonstrate to the satisfaction of the Agency that the products of atmospheric reaction have no effect on the health or welfare of man. Otherwise, the conservative assumption - that no chemical removal occurs - should be used.

For modeling purposes, incinerators should clearly be considered as point sources. In most cases, only one source is to be modeled, but in some cases, it is appropriate to model the combined impact of several sources using a multi-source model.

Finally, the averaging time of interest is one year in this example which is oriented toward limiting the occurrence of cancer. Carcinogenic effects are a function of cumulative exposure to a compound, and so it is appropriate to use a long-term average

concentration (i.e., a one-year average) to estimate long-term exposure to a compound. For pollutants which exhibit other forms of toxicity such as TLV's, other averaging times, appropriate to the type of health effect, should be selected.

The Guideline on Air Quality Models[2] specifically addresses only those pollutants for which a National Ambient Air Quality Standard has been set. However, the hazardous pollutants being considered here are analogous to SO_2 and should be modeled as being chemically inert or as having first-order decay. Thus, the techniques used for incinerators emitting carcinogens should be in accordance with the guideline recommendations for estimating annual average concentrations of SO_2 resulting from one or more point sources.

When just one incinerator is being considered, the guideline recommends several suitable screening techniques. A useful discussion of many of these techniques is provided in Volume 10 (Revised) of the Guidelines for Air Quality Maintenance Planning and Analysis, entitled Procedures for Evaluating Air Quality Impact of New Stationary Sources.[15] This document provides step-by-step approaches for making screening estimates of concentrations for cases of flat terrain with no significant meteorological complications and for more complex situations. The Guideline on Air Quality Models[12] also references several other documents which discuss screening techniques, some of which are useful for situations not discussed in Volume 10.

If a refined modeling technique is to be used and if one incinerator is being considered, the guideline recommends using

the Single Source (CRSTER) Model.[16] Alternatively, other models with other output formats may be used.

Screening techniques are not generally available for multisource situations. In the multisource situation direct use of a refined multisource model is necessary. Recommended models of this type for estimating annual average concentrations include the Climatological Dispersion Model (CDM/CDMQC) for urban cases[17]. For rural cases, models described in the Summary Report of the Regional Workshops on Air Quality Modeling are recommended[18].

Data Collection

If refined modeling techniques are used, it is necessary to obtain several types of data. The Guideline on Air Quality Models discusses four types of data required by air quality models: source data, meteorological data, receptor locations, and background concentration. Source data are primarily used to estimate emissions rates and plume rise. It may be necessary to model more than one operating condition. The meteorological data includes wind speed, wind direction, atmospheric stability, and mixing height. These data must be representative of the meteorological conditions at the source. Five years of data should be used to insure the data are representative. Receptor locations must be be carefully chosen so that the maximum concentrations is estimated. The guideline gives specific recommendations on locating receptors. Background concentrations are important when the sum of the background concentration plus the source impact is not allowed to exceed a given concentration.

One additional type of necessary data is information on whether special circumstances exist that will affect atmospheric dispersion. For example, it is necessary to determine if the plume is affected by complex terrain, lake/sea breezes, fumigation, aerodynamic downwash, or deposition. If so, it may be necessary to use a model specially designed for those circumstances.

Recommended Procedures

The following procedure for determination of emission limitations on hazardous substances is generally recommended:

(1) A screening analysis will be performed to estimate highest atmospheric concentrations of all compounds designated as hazardous that are to be emitted by the incinerator (this analysis will assume that the incinerator destroys 99.99% of the POHC's introduced into the incinerator).

(2) Using the health effects information identified for hazardous compounds emitted, the increase in cancer risk caused by the highest concentrations estimated in step (1) for each hazardous substance is calculated. If more than one substance is involved, increases are summed to find a total increase in cancer risk.

(3) If the total increase in cancer risk caused by the incinerator is less than or equal to an acceptable increment, then 99.99% destruction and removal may be considered adequate. If the total increase in cancer

risk is greater than the acceptable increment, then steps (1) and (2) should be repeated using different values of acceptability. Additional modeling may be desirable also.

(4) If a more refined modeling technique also shows an increase in cancer risk that exceeds the acceptable increment, maximum allowable emission limits must be determined. These limits may be calculated by assuming a linear relationship between emissions and risk.

(5) After a maximum allowable emission rate is determined from the air modeling and health risk computations, the permit writer must exercise his best engineering judgment to determine how the emission limit will be controlled. He may do this by requiring 1) a demonstration of a higher DRE, 2) specifying in the permit a maximum feed rate limit for one or more wastes or their components, or 3) a combination of both 1) and 2).

It should be noted that in some situations the guideline does not recommend both a screening technique and a more refined model. First, there are situations where applicable refined models are not available. When possible, an attempt should be made to develop refined techniques; however, in many cases screening techniques will be the only viable option. Second, there are also situations, most notably when two or more sources affect the same area, when no suitable screening techniques exist. If one of the types of modeling techniques is not possible, the above procedure should be shortened accordingly.

Figures 5-8 give flow diagrams of the analyses necessary to determine emissions limitations for incinerators of hazardous wastes. Four possible situations exist: a single incinerator emits one hazardous substance (Fig. 5), one incinerator emits several hazardous substances (Fig. 6), multiple incinerators emit the same single hazardous substance (Fig. 7), and multiple incinerators emit several hazardous materials (Fig. 8). The analyses for the cases of a single incinerator are essentially equivalent to the procedure described previously. Note that "estimated concentration" is shorthand for the highest annual average concentration chosen from a number of receptors. The analysis for the case of several incinerators emitting the same one substance is also similar to the procedure discussed above except that no screening analysis is performed.

As Figure 8 illustrates, the analysis for the case where several incinerators emit several hazardous substances should be conducted somewhat differently from other analyses to facilitate location and determination of the maximum risk. In these analyses, emissions (units of, e.g., g/sec) are used in the model to estimate ambient concentrations (e.g., $\frac{g}{sec} \times \frac{sec}{m^3} = \frac{g}{m^3}$),* and concentrations are then converted into risk factors (e.g., $\frac{g}{m^3} \times \frac{\text{risk units} \cdot m^3}{g}$ = risk units). In the multiple incinerator, multiple substance case, the emission rate for each substance should be multipled by the concentration-to-risk conversion factor

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* $\frac{sec}{m^3}$ are the units of dilution (X/Q).

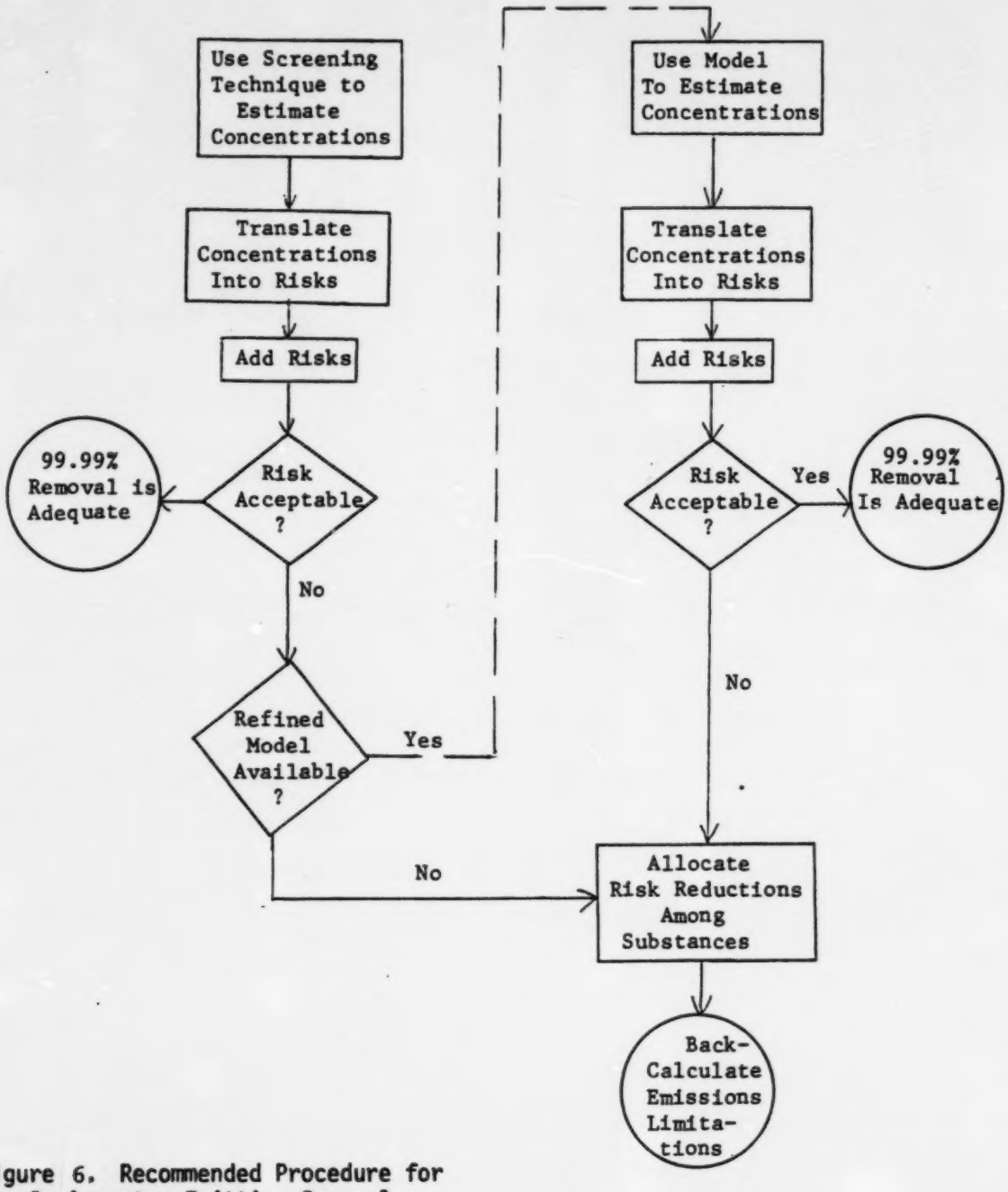

Figure 6. Recommended Procedure for One Incinerator Emitting Several Hazardous Substances.

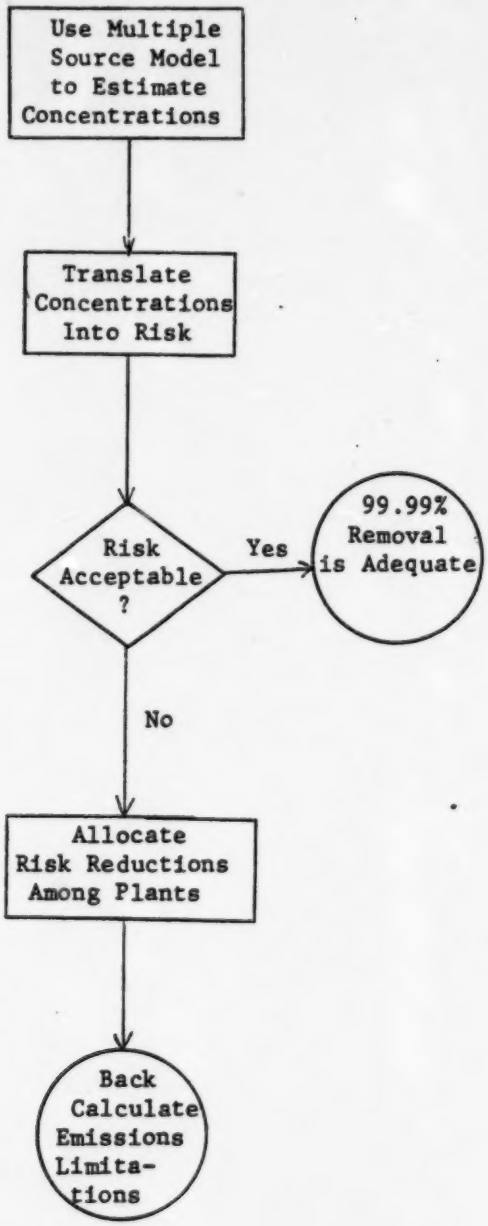

Figure 7. Recommended Procedure for Several Incinerators Emitting One Hazardous Substance

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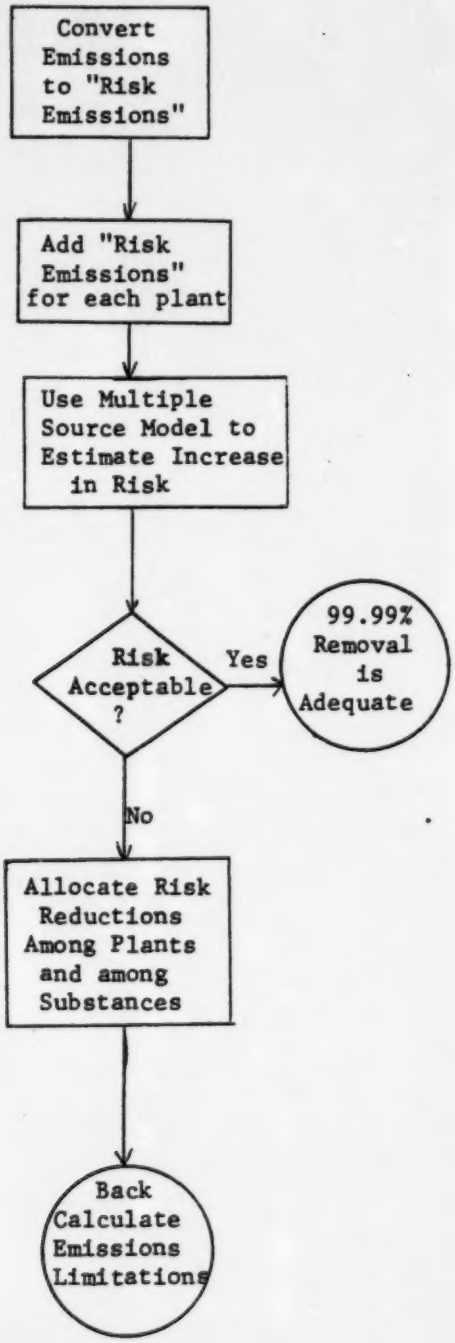
Convert Emissions to "Risk Emissions"
Add "Risk Emissions" for each plant
Use Multiple Source Model to Estimate Increase in Risk
Risk Acceptable ?
Yes
99.99% Removal is Adequate
No
Allocate Risk Reductions Among Plants and among Substances
Back Calculate Emissions Limitations

Figure 8. Recommended Procedure for Several Incinerators Emitting Several Hazardous Substances

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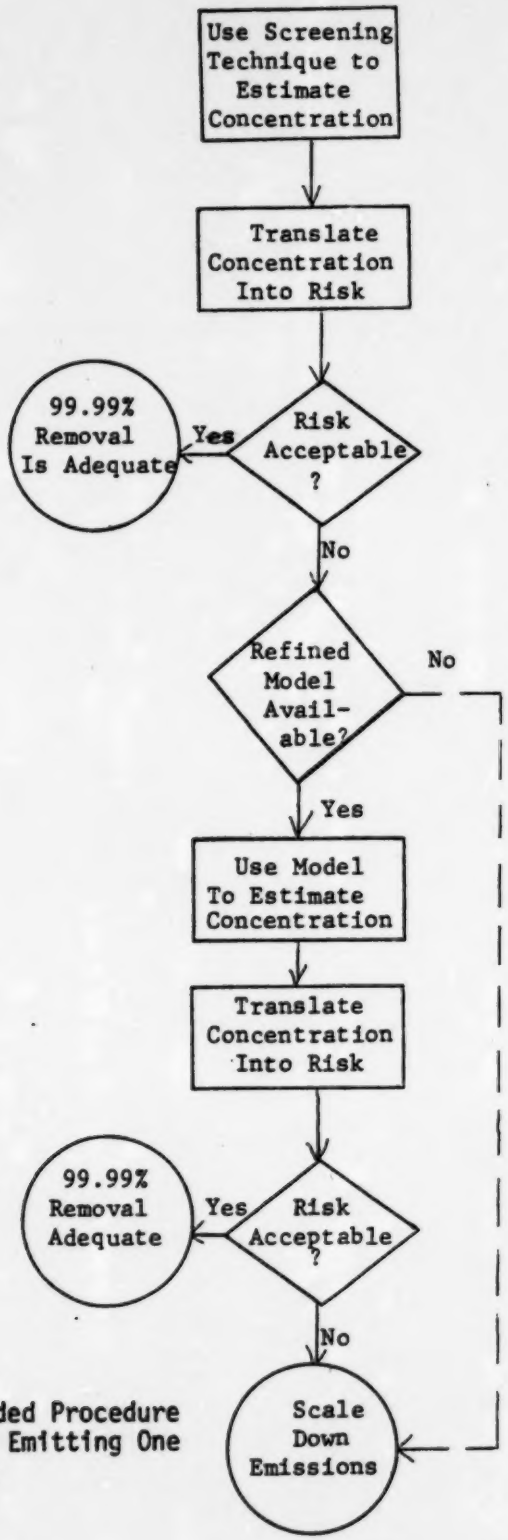

Figure 5. Recommended Procedure for One Incinerator Emitting One Hazardous Substance

for the substance. This generates quantities labeled here as "risk emissions" (e.g., $\frac{g}{sec} \times \frac{\text{risk units} \cdot m^3}{g} = \frac{\text{risk units} \cdot m^3}{sec}$).** Multiplying the emissions by a risk weighting places the emissions of all substances on a common basis. The "risk emissions" for each plant can then be added to give a total "risk emission" for the plant. These "risk emissions" may be used in the model to estimate risk directly (e.g., $\frac{\text{risk units} \cdot m^3}{sec} \times \frac{sec}{m^3}$ = risk units). Using this approach, the task of locating the receptor with the highest overall risk burden is greatly simplified.*** Using the total "risk emissions" as input (in place of emission rate) the multisource model output will display risk factors which have already been summed for all species and all incinerators.

The "risk-emission" approach is not required for simpler cases since there is no ambiguity about the location of the maximum risk. (In the case of one incinerator emitting several substances, the maximum concentrations of the substances can all be expected to occur at the same location).

** As an example: assume that the emission rate is 2 g/sec and that a concentration of 10^{-6} g/m^3 causes a risk factor of 10^{-7}. Then the "risk emission" would be $2 \times 10^{-7}/10^{-6} = 0.2$ risk units-m^3/sec.

*** Location of highest risk is difficult using the conventional approach. It is likely that different substances will have their maximum concentrations at different locations. The location of greatest total risk may not correspond to the location of any of the individual substance maxima. Thus determining the maximum total risk would necessitate a tedious process of converting concentration to risk factors at a large number of receptors.

One other noteworthy feature of Figures 5-8 is that once modeling is performed to estimate risks based on 99.99% destruction, no further modeling is necessary to determine emissions limitations. Modeling essentially provides a linear relationship between emissions and concentrations. As a result, a given percentage reduction in concentration (and associated risk) is achieved by reducing emissions by the same percentage. A word of caution, however; if two or more incinerators are controlled to different degrees, the location of the maximum concentration may change. In such cases, it is advisable to confirm, possibly via an additional model simulation, that the proposed emission reductions will in fact result in risks at all locations being within acceptable limits.

It is important to note that the specific location of the point or points of maximum concentration is not important to the strategy proposed in this document. It is sufficient only to know (1) that they do exist and (2) what the worse case concentration(s) are or could be. With these two facts, the health impact (risk) can be determined regardless of whether a receptor is in fact located at the point of maximum concentration.

One exception to the above strategy might be envisioned. If an incinerator were located in a remote area where extensive air modeling could demonstrate that no person(s) would be significantly impacted under any meteorological condition (at the point of maximum concentration) then a less restrictive emission rate and accompanying higher ambient air concentration could be allowed.

4. Comparison of Regulations to Regulations Under the Clean Air Act

It is useful to place these regulations in the context of general approaches to managing atmospheric contamination and in the context of comparable regulations under the Clean Air Act. The management of atmospheric contamination can proceed by either the air quality management approach or the emissions management approach. In the air quality management approach, the regulations specify a target air concentration, and modeling is used on a case-by-case basis to determine the emissions limitations necessary to avoid violating the target air concentration. In the emissions management approach, the regulations directly specify emissions limitations (e.g., pounds of emissions per ton of manufactured product) without regard to the case-by-case impact on air quality.

Regulatory actions pursuant to the Clean Air Act provide examples of both types of management approaches. Examples of the air quality management approach include the National Ambient Air Quality Standards (NAAQS) and the program for Prevention of Significant Deterioration (PSD). The NAAQS are concentrations not to be exceeded more than once per year in any location, and the increments under the PSD program represent maximum allowable increases in concentration for areas meeting NAAQS. Examples of the emissions management approach include New Source Performance Standards (NSPS) and National Emissions Standards for Hazardous Air Pollutants (NESHAP). The NSPS are emission standards for pollutants having an established NAAQS, and the NESHAP are emission

standards that apply without regard to the case-by-case impact on air quality.

These proposed regulations represent a mix of the air quality management approach and the emissions management approach. That is, sources of hazardous pollutants must meet an emission standard based on a 99.99% removal but also may be evaluated for air quality impact on a case-by-case basis to assess the need for more stringent emissions limitations. These regulations differ from regulations under the Clean Air Act in that these regulations are concerned with the combined effects of several pollutants rather than the effect of each pollutant individually. Thus, these regulations could, for example, limit the combined increase in risk to cancer rather than limiting concentrations of individual chemicals. However, these regulations are similar to the regulations for PSD in that the concern is with the degradation of air quality beyond the existing base line and that if more than one source locates in an area the combined impact must be considered.

5. Use of the Linearized Multistage Model for Cancer Induction

Definitions

- Carcinogenic potency: The proportionality constant, B_H, between the lifetime average daily exposure concentration to an agent, C, and the incremental lifetime risk of cancer due to that exposure alone, R. It is defined by the equation $R = B_H C$. The numerical value of B_H is determined by the human or animal data on

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the carcinogenic effect of the agent. The units of B_H must be compatible with the units of C, so that the product of B_H and C is a dimensionless quantity, since R is a probability and has no units. B_H is the slope of a linear potency curve which passes through the intercept (C=0, R=0).

- Threshold: A certain exposure, usually expressed as a concentration in air or water, below which a given adverse effect does not occur.
- Threshold Limit Value (TLV): An air concentration of an agency established by the American Council of Government Industrial Hydienists, below which continued exposure would not result in adverse impact on health of workers. Therefore, TLV is a threshold concentration.

Induction

Defining the health impacts of exposure to a given hazardous substance relies on the use of a dose response model for cancer induction. The dose response model has been developed by the Cancer Assessment Group of EPA and others. It has been used in other ongoing and planned EPA regulations, including National Emissions Standards for Hazardous Air Pollutants (NESHAPS), groundwater quality standards, and for other purposes.

In quantitatively assessing the public health risk of air emission sources, the ambient air concentration of each toxic chemical is one of the most critical parameters. For toxic effects besides cancer and mutagenesis, most authorities agree

that a threshold concentration exists below which no response occurs. If the chemicals have caused cancer in animal experiments, they generally are regarded as potential human carcinogens, and the risk is proportional to the long-term average concentration, the proportionality constant of this risk being called B_H. Refer to Table 2 for potency (slope) values developed to date.

The lifetime cancer incidence in the general U.S. population from all causes is about 0.25, and the extra risk due to exposure to a chemical, R (called the incremental cancer risk), is equal to $R = B_H \cdot C$, where C is the lifetime average concentration of that chemical. In cases where several chemicals are present, the risks may be assured to be additive, so that the total risk can be represented by:

$$R = \quad B_{Hi}\ C_i$$

R is proportional to the total dose a person receives in his/her lifetime, and is expressed in terms of lifetime average daily exposure. According to this model, a person exposed to a given concentration for just n years out of an assumed lifetime of 70 years, will have a risk of only n - 70 times the risk experienced by a person exposed to the same degree for a whole lifetime. If the exposure changes during the lifetime, then the time-weighted average is the appropriate quantity to use for C_i.

Table II

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Beryllium	2.70×10^{-1}
Cadmium	1.90×10^{-3}
Diethyl-Nitrosamine (DEN)	7.18×10^{-2}
Dimethyl-Nitrosamine (DMN)	4.35×10^{-3}
Ethylene Dibromide	5.90×10^{-4}
Ethylene Dichloride	1.20×10^{-5}
Ethylene Oxide	1.20×10^{-4}
Formaldehyde	6.53×10^{-5}
Manganese	4.0×10^{-4}
Nickel	1.80×10^{-3}
N-nitroso-N-ethylurea (NEU)	6.66×10^{-3}
N-nitroso-N-methylurea (NMU)	0.67
Perchloroethylene	7.60×10^{-6}
TCDD	121.428
Trichloroethylene	8.80×10^{-7}
Vinyl Chloride	1.43×10^{-3}
Vinylidene Chloride	5.93×10^{-5}

The potency factors, B_H, are estimated from epidemiological data where possible and from chronic animal carcinogenic experiments when appropriate human evidence is not available. Methods for deriving B_H are discussed in the Water Quality Methodology Paper.(8,10)

In the regulation of emissions from incinerators, an approach presented as an example is to first establish an acceptable or target lifetime individual risk level, and from that calculate what air concentration limit must prevail in order to keep the lifetime risk below the target level. By means of air dispersion modeling, the upper limit ambient concentrations are converted into maximum emission rates from the incinerator stack. This, in turn, is translated into incinerator waste feed rates.

Because each chemical has its own characteristic carcinogenic potency, B_H, the total risk will be determined by a potency-weighted sum of ambient air concentrations. This sum dictates the critical parameters affecting the incinerator operation. A technique is discussed in the previous section.

Acceptable Risk

Two quantitative measures of risk have been used by the Agency in evaluating carcinogenic hazards to populations exposed to the agent. These are: (1) the individual lifetime cancer risk, which is defined as the probability that an exposed person will die of cancer, as opposed to other causes, as a result of exposure, and (2) the number of cancer cases per year which can be attributed to the exposure. The individual risk depends on the carcinogenic effectiveness of the compound, which is called

its potency, and the concentration of the agent in the exposure medium, whereas the number of cases depends on the individual risk and the size of the exposed population.

In deciding what risk is acceptable from a public health protection point of view, the EPA regulatory offices have concentrated on the individual risk. For example, the Pesticides Office is considering a lifetime risk of 10^{-6} as acceptably low in the case of nitrosamine contamination of pesticide products. The Water Quality Office is requiring the reporting of hazardous material spills into navigable water that could be used as a source of drinking water if the risks are greater than 10^{-6}. In the Food and Drug Administration regulations of animal feed additives that could cause residues of carcinogenic substances in edible meat, a risk of less than 10^{-6} is considered safe enough to require no use restriction. The water quality criteria for the protection of human health were based on a risk range of 10^{-7} to 10^{-5}.(10)

The attitude of many scientists and policy makers is that a risk of less than 10^{-7} is usually too small to justify the resources required to issue and enforce a regulation. A risk of greater than 10^{-4} is usually considered serious enough either to take regulatory action or to require a determination that the costs of control are prohibitively large. Within the range of roughly 10^{-7} to 10^{-4} the acceptability of a risk is usually a result of cost-benefit balancing. The Agency has not made a judgment on what constitutes an "acceptable" risk level. The reader is referred to the Water Quality Criteria documents (10) and other sources for more background.

For noncarcinogenic substances it is generally believed that risks are zero if the exposure is less than a certain low concentration, or threshold.

For these two classes of compounds the following approaches could be used: (1) carcinogens with no currently available potency value could be assigned a value based on their structural similarity to chemicals for which a potency value is known, and (2) noncarcinogens could be treated as threshold pollutants and an acceptable ambient air concentration could be established as a certain fraction (say one-tenth) of the Threshold Limit Value (TLV). Adopting the unmodified TLV as the acceptable concentration for general population exposure is not advised because it is designed for healthy people (factory workers) who voluntarily assume the risk of exposure in order to work at their jobs. Multi-media environmental goal values (MEG's) could also be used.[25]

For chemicals without an established TLV, the procedure outlined in the health methodology of the Water Quality Criteria documents[10] could be followed. It is a procedure for setting acceptable limits based on toxicity information.

Multistage Model

The mathematical model chosen for extrapolation of cancer risks from the high doses used in animal experiments to low doses of environmental exposure is the linearized multistage model. This approach is described in the Water Quality Criteria document procedures.[10] Although that document describes the procedure in detail, the major features are repeated here.

The model is a general curve-fitting procedure which can fit a monotonically increasing function of dose to the animal tumor incidence data. The assumption is made that the tumor incidence is linearly related to the dose with no threshold. This is in accord with the assumption of other regulatory agencies, as manifested by the Interagency Regulatory Liaison Group (IRLG) guidelines for the evaluation of carcinogenic risk.[19] For some compounds, a threshold at low doses might exist. If this were the case, then the extrapolation procedure used here is regarded as giving a reasonable upper limit of the risk at low doses (i.e., is conservative). Future research on mechanisms of carcinogenic action might result in a more definitive quantitative statement of risk. The structure of the proposed regulation would allow use of any technically acceptable approach.

Fundamental Cancer Model Assumptions

The linear non-threshold model assumes that the lifetime total dose is the basis for the risk estimation. In the animal experiments which form the basis for the procedures the dose rate is usually constant throughout the lifetime. If the same lifetime dose were given within a short fraction of the lifetime, then the result would be the same under the linear assumption. However, some evidence exists that large amounts given within a short time cause more damage, at least for acute toxicity effects, than the same amount spread out over a much larger time. There is some evidence that these non-linear dose rate effects also occur in carcinogenesis experiments, at least in the one case of

vinyl chloride. However, the information on this point is very sparse. The only generality that can be made is that as long as the dose rate for environmental exposures is less than the equivalent dose rate in the lifetime animal bioassay with constant dosing, the potency factors derived according to these procedures can be used. But if the dose rates become significantly larger, then calculated risks might be too small. The correction factors for these short range high dose situations are unknown. It is unlikely that environmental doses would be higher than experimental doses.

The instances of pulsed doses to populations which are large enough to exceed the animal dose rate are expected to be very rare, since animal doses are typically many orders of magnitude larger than environmental doses.

6. Examples and Sample Calculations for the Variance

This section presents data and examines calculations to illustrate how the variance (override) approach may work. In general, conservative approaches have been adopted to illustrate certain points. Different acceptable risk levels and model assumptions have been selected to illustrate the sensitivity of the approach.

For assessment of carcinogens the process begins with the types of data illustrated in Table 2. "The Carcinogenic Assessment Group's Preliminary Carcinogenic Potency Estimates on Compounds included in Air Program". The data are used in the following equation:

$$\text{Concentration} = \frac{\text{Risk}}{\text{Potency (slope)}}$$

Where:

Concentration = The lifetime average exposure level to a carcinogenic substance.

Risk = The incremental increase in cancer deaths.

Potency = The estimated slope of the straight line which passes through the intercept point of the dose-risk curve.

By using this relationship, calculation of the long-term air concentrations for any risk level can be done quickly. As seen in Table 2, a wide range of potency slopes have been determined all the way from trichlorethylene with a value of 8.8×10^{-7} $(ug/m^3)^{-1}$ to TCDD with a potency of about 121 $(ug/m^3)^{-1}$.

The next steps are illustrated in Table 3. Using the potency slope (B_H) for a number of organic comounds and five metals, the air concentration (C) in mg/m^3 is calculated for a risk of 1×10^{-5}. Next a dispersion model is selected, assumptions are made for the model and the allowable stack emission rate (E) is determined. In the last column the maximum allowable waste feed rate is calculated based on the maximum allowable emission rate (E). This calculation is straight-forward and is also shown in Tables III and IV for different air dispersion model conditions and risk levels.

Table 4 illustrates the impact of different conditions imposed in the air modeling exercise. In this table the risk is the same (1×10^{-5}) but the stability class is more stringent and the effective stack height has been lowered from 150 meters to 30 meters. The allowable emission rate and thus the allowable

TABLE 3 : ESTIMATION OF ALLOWABLE MASS FEED BASED ON A RISK OF $1x10^{-5}$, ASSUMING A DRE OF 99.99%

Compounds	BH* Potency Slope $(mg/m^3)^{-1}$	C Concentration(mg/m^3) Associated with 10^{-5} risk	E** Allowable Stack Emission rate Rate (mg/sec)	E (g/hr)	Allowable Waste Input (kg/hr) Assuming 99.99% Efficiency
Acrylonitrile	8.5×10^{-2}	1.18×10^{-4}	59	212.4	2124
Allyl Chloride	2.66×10^{-3}	3.76×10^{-3}	1880	6768	67680
Dimethyl-Nitrosamine	4.35	2.30×10^{-6}	1.15	4.14	41.4
N-nitroso-N-Methylurea	670	1.49×10^{-8}	7.45×10^{-3}	2.68×10^{-2}	0.268
Manganese	0.40	2.50×10^{-5}	12.50	45	450
Nickel	1.8	5.56×10^{-6}	2.78	10	100
Beryllium	270	3.70×10^{-8}	1.85×10^{-2}	6.66×10^{-2}	0.666
Cadmium	1.9	5.26×10^{-6}	2.63	9.47	94.70
TCDD	121428.57	8.23×10^{-11}	4.12×10^{-5}	1.48×10^{-4}	1.48 x
Trichloretylene	8.80×10^{-4}	1.14×10^{-2}	5700	20520	205200

* These are preliminary estimates and are subject to change

** Assumptions: 1. Sunny summer afternoon, wind speed measured at 10 meters is 4 m/sec (stability class B).

2. Effective stack height is 150 meters.

3. Open flat country.

4. Single point source.

(64)

TABLE 4 : ESTIMATION OF ALLOWABLE MASS FEED BASED ON RISK APPROACH, ASSUMING A DRE OF 99.99% AND A RISK OF $1x10^{-5}$

Compounds	BH* Potency Slope $(mg/m^3)^{-1}$	C Concentration(mg/m^3) Associated with 10^{-5} risk	E** Allowable Stack Emission rate Rate (g/hr)	Allowable Waste Input (kg/hr) Assuming 99.99% Efficiency
Acrylonitrile	8.5×10^{-2}	1.18×10^{-4}	11.3	113
Allyl Chloride	2.66×10^{-3}	3.76×10^{-3}	361	3610
Dimethyl-Nitrosamine	4.35	2.30×10^{-6}	0.22	2.2
N-nitroso-N-Methylurea	670	1.49×10^{-8}	1.34×10^{-3}	1.34×10^{-2}
Manganese	0.40	2.50×10^{-5}	2.4	24
Nickel	1.8	5.56×10^{-6}	0.53	5.3
Beryllium	270	3.70×10^{-8}	3.6×10^{-3}	3.6×10^{-2}
Cadmium	1.9	5.26×10^{-6}	0.50	5.0
TCDD	121428	8.23×10^{-11}	7.9×10^{-6}	7.9×10^{-4}
Trichloretylene	8.80×10^{-4}	1.14×10^{-2}	1094	10,940.

* These are preliminary estimates and are subject to change

** Assumptions: 1. Wind speed is 4 m/sec (stability class A).

2. Effective stack height is 30 meters.

3. Open flat country.

4. Single point source.

feed rate at a 99.99% DRE has been dramatically reduced by a factor of nearly 20 times. These examples illustrate the dramatic impact of stack height on ground level concentrations of emissions.

Table 5 shows the same calculations using the same air dispersion model but decreasing the risk level to 1×10^{-6}. This change in risk level causes both the allowable emissions rate and the maximum feed rate at 99.99% DRE to drop by a factor of 10. This illustrates the sensitivity of the procedure to the selection of an acceptable risk level.

As examples of how this analytical process would impact a real world incinerator, the restriction on the destruction of TCDD containing waste from 2,4, 5-T production is determined as follows:

- The waste contains 300 ppm of TCDD
- From Table III, the allowable feed rate at 99.99% DRE is 7.9×10^{-4} kg/hr
- 7.9×10^{-4} kg/hr (TCDD) $\div$ 300 ppm = 2.63 kg/hr of waste
- Thus an incinerator would be restricted to a maximum feed rate of 2.6 kg/hr (5.810/hr) to result in a risk of 1×10^{-5}.

An incinerator burning this waste would be restricted to a very low feed rate of the 2,4, 5-T waste. If the owner or operator of the incinerator could demonstrate that a higher DRE could be achieved then a higher feed rate could be allowed. In cases such as this the permitting official would have the option of either requiring a higher DRE, restricting the feed rate of the waste or a combination of both.

TABLE 5 : ESTIMATION OF ALLOWABLE MASS FEED BASED ON A RISK OF $1x10^{-6}$ ASSUMING A DRE OF 99.99%

Compounds	BH* Potency Slope $(mg/m^3)^{-1}$	C Concentration(mg/m^3) Associated with 10^{-6} risk	E** Allowable Stack Emission rate Rate (g/hr)	Allowable Waste Input (kg/hr) Assuming 99.99% Destruction and Removal Efficiency
Acrylonitrile	8.5×10^{-2}	1.18×10^{-5}	1.1	11.3
Allyl Chloride	2.66×10^{-3}	3.78×10^{-4}	36	361
Dimethyl-Nitrosamine	4.35	2.3×10^{-7}	0.02	0.22
N-nitroso-N-Methylurea	670	1.49×10^{-9}	1.34×10^{-4}	0.001
Manganese	0.40	2.50×10^{-6}	0.24	2.4
Nickel	1.8	5.56×10^{-7}	0.05	0.5
Beryllium	270	3.70×10^{-9}	3.6×10^{-4}	0.004
Cadmium	1.4	5.26×10^{-7}	0.050	0.5
TCDD	121428	8.23×10^{-12}	7.9×10^{-6}	7.9×10^{-5}
Trichloretylene	8.80×10^{-4}	1.14×10^{-3}	109.4	1,094

* These are preliminary estimates and are subject to change

** Assumptions:
1. Wind speed is 4 m/sec (stability class A).
2. Effective stack height is 30 meters.
3. Open flat country.
4. Single point source.

7. Use of the Carcinogen Risk Assessment Strategy

This discussion explains how the risk assessment approach may be used from two directions:

(a) Starting with an acceptable risk statement and working backward to a stack emission limit (i.e., a limit on hazardous waste feed to the incinerator).

(b) Initially stipulating emission rates and deriving exposure concentrations which are related to an acceptable risk statement.

The approach adopted for the purpose of the standard whether manipulated in the "forward" or "backward" mode is a conservative approach from the point of view of exposure of individuals to hazardous materials in the ambient air. It is conservative in the sense of once having chosen an acceptable risk limit, e.g., 1×10^{-6}, each individual is assumed to be exposed to that degree regardless of where in the immediate area that individual might spend most of his time. A complete dispersion model analysis of the area surrounding a hazardous waste incinerator would clearly result in different risk exposures depending on proximity to the incinerator. The dispersion model calculation is related basically to a zone of maximum concentration downwind from an incinerator stack and the basis for the entire risk assessment analysis is therefore, this zone of maximum exposure. Thus, the conservative nature of the approach. Each individual is assumed to be exposed at a risk level in this example of 1×10^{-6} even though a more detailed analysis, both nearer to and farther from the incinerator stack could possible result in a lower exposure risk.

As a part of the overall risk assessment, an analysis of total population exposure could be performed. Such an analysis would yield the probability of health damage, e.g., cancer induction for the people in the general surrounding area, or even the Nation as a whole based on this one source of hazardous material. Such analyses are time consuming and difficult to perform. The result of such analyses do not enhance the protective aspect of the risk assessment approach, since the individual incremental risk approach is conservative.

To further understand how the override approach would affect decisions for some typical cases, the reader is referred to Table 6 which presents results of several sample calculations. For these examples an acceptable risk level of 1×10^{-6} (probability of increased risk of contracting cancer for an individual during a 70 year lifetime) has been chosen to perform calculations. Other risk levels could have been used. The approach to override or underride the DRE of 99.99% is suggested for use only where dose-response or threshold data are already available.

Table 6 presents four manufacturing processes representing several wastes streams (column 1) and typical or average discharge quantities for these wastes. From available dose-response data, a choice of an acceptable risk level will result in associated ambient air concentration (column 3), and from this a stack emission rate of the chemical may be estimated (column 4). The calculated incinerator feed rate is then derived (column 5).

TABLE 6

SAMPLE CALCULATIONS COMPARING ALLOWABLE INCINERATOR FEED RATES AT $1x10^{-6}$ RISK WITH TYPICAL PLANT WASTE PRODUCTION RATES

(1) Manufacturing process waste	(2) Typical or Average Plant Waste Component (MT/yr.)	(3) Air Concentration Associated with $1x10^{-6}$ Incremental Risk (mg/m^3)	(4) Modeled Emission Rate (gm/hr)	(5) Calculated Incinerator Feed Rate (MT/yr.) 99.99% DRE	(6) Limitations for on-site Incineration
Vinyl Chloride Monomer plant wastes(19)	544-1,1,2 Trichloroethane	$1.13x10^{-3}$	108	8510	None
Electronic components Manufacturing Solvents(20)	326-Ethylene dichloride	$8.3 x10^{-5}$	8.0	631	
	1.2-1,1,1, Trichloroethane	$1.13x10^{-3}$	108	8510	None
	1.06 Perchloroethylene	$1.3x10^{-4}$	12.6	993	
Textile Processing Wool Scouring Sludge (21)	0.6-Manganese	$2.5x10^{-6}$	0.24	0.0019*	If 100% of metals were emitted, on-site incineration would be prohibited
	0.04-Nickel	$5.56x10^{-7}$	0.53	$4.2x10^{-4}$*	
	0.0003-Arsenic	$3.3x10^{-7}$	0.032	$2.6x10^{-4}$*	

TABLE 6 (CONT.)

SAMPLE CALCULATIONS COMPARING ALLOWABLE INCINERATOR FEED RATES AT $1x10^{-6}$ RISK WITH TYPICAL PLANT WASTE PRODUCTION RATES

(1) Manufacturing process waste	(2) Typical or Average Plant Waste Component (MT/yr.)	(3) Air Concentration Associated with $1x10^{-6}$ Incremental Risk (mg/m^3)	(4) Modeled Emission Rate (gm/hr)	(5) Calculated Incinerator Feed Rate (MR/yr.) 99.99% DRE	(6) Limitations for on-site Incineration
Petroleum Refining (Total of 17 waste streams(1)	0.0275-Arsenic	$3.3x10^{-7}$	0.032	$2.6x10^{-4}$*	
	0.32 Nickel	$5.6x10^{-7}$	0.053	$4.2x10^{-4}$*	If 100% of metals were emitted, the total waste stream could not be incinerated at $1x10^{-6}$ risk

* For these calculations it was conservatively assumed that 100% of the metal feed passed through into the emissions.

(a) Air Model Assumptions:

1. Effective Plume Height - 30 meters
2. Stability Class A
3. Wind Speed - 4 m/s

The conclusions in column (6) were developed based on a comparison of the calculated incinerator feed rate (column 5) with the quantity of waste component in the typical waste stream (column 2) at a destruction and removal efficiency of 99.99%.

In the case of vinyl chloride monomer production using a 1×10^{-6} incremental increase in cancer risk and 99.99% DRE of the waste components, the 1, 1, 2 Trichlorethane waste component would not be restrictive. Similarly, the average quantities of solvents from electronic component manufacturing could be incinerated with no restrictions.

The third and fourth cases shown in Table 6 indicate significant problems. In these examples, the metals content of the textile sludge and the petroleum refining wastes would prohibit incineration of the total quantity of these wastes assuming that 100% of the metals in the waste were emitted to the atmosphere. However, if only a small amount of these metals were emitted and most (say 99.99%) were retained either in the ash or in the scrubber then these wastes could be incinerated on-site with no restrictions.

The variance approach may be viewed in another way. Incinerators will be required to meet the 99.99% DRE for a wide variety of wastes. It is instructive to examine the application of the DRE to some typical wastes. Table 7 shows the results of applying DRE = 99.99% to the same wastes for which the previous calculations were performed to yield allowable incinerator feed rate, starting with predetermined acceptable risk levels. In

TABLE 7

RISK EVALUATION FOR 30,000 METRIC TON/YEAR INCINERATOR BURNING HAZARDOUS WASTE

(1) Waste	(2) Hazardous Components	(3) Emission Rate*	(4) Ambient Concentration from Air Model Calculation	(5) Incremental Risk from Dose Response Calculation
30,000 MT/yr -	MT/yr.	g/hr	mg/m^3	
Petroleum Refining(1)	0.48-Arsenic	3.1×10^{-7}	3.2×10^{-12}	9.6×10^{-12}
	.561-Nickel	3.6×10^{-6}	3.8×10^{-8}	6.8×10^{-8}
Vinyl Chloride (19) Monomer	1428-1,1,2 Trichloroethane	18.1	1.9×10^{-4}	1.7×10^{-7}
	857-ethylene dichloride	10.9	1.1×10^{-4}	1.3×10^{-6}
Textile(21) Wool Scouring Sludge	0.038-Nickel	0.24	2.5×10^{-6}	4.5×10^{-6}
	0.003-Arsenic	0.02	2×10^{-7}	6×10^{-7}
	0.62-Manganese	3.9	4.1×10^{-5}	1.6×10^{-5}
Electronic Components Waste Solvents (20)	8760-Trichloroethylene	111.0	1.1×10^{-3}	1×10^{-6}
	1830-Perchloroethylene	23.0	2.4×10^{-4}	1.8×10^{-6}

* For Organics emission rate is based on 99.99% DRE; for metals a 95% removal rate is assumed.

this case, an average incinerator capacity (off-site) was determined from a survey of 23 incinerators[23] to be 30,000 wet Mt/yr. The assumption is made that the incinerator will operate at full capacity over the period of one year. The quantity of POHC discharged under these burn conditions is then modeled for dispersion in the ambient air to the receptor. The resultant risk level (column 5) is then calculated based on the ambient air concentration at the receptor determined through dispersion modeling.

Proposed Regulatory Language

§264.343 Performance Standards

(e) After consideration of the factors listed in paragraph (g) of this Section, the Regional Administrator may, on a case-by-case basis, establish performance standards which are either more or less stringent than those required by paragraphs (a) and (d) of this Section based on a finding that:

(1) More stringent standards are necessary because the emission rates achieved by the application of the performance standards otherwise required by this Section may pose an unacceptable risk to human health and the environment, or

(2) Less stringent standards will achieve emission rates which do not pose an unacceptable risk to human health and the environment.

(g) The findings under paragraphs (e) and (f) of this Section will be made after evaluating the following data, which the Regional Administrator may require from the permit applicant:

(1) Emissions of POHC's, hazardous combustion by-products, metals, and hydrogen halides, including:

(i) Mass emission rates from the stack, and

(ii) Concentration in the gas stream exiting the stack;

(2) Air dispersion estimates for these substances, including:

(i) Meteorological data,

(ii) Description of the air dispersion models,

(iii) Assumptions underlying the air dispersion models used;

(3) Expected human and environmental exposure, including:

(i) Topographic considerations,

(ii) Population distributions,

(iii) Population activities, and

(iv) Modes, intensity and duration of exposure;

(4) Consequences of exposure, including:

(i) Dose-response curves for carcinogens,

(ii) Health effects based on human or animal studies for other toxic constituents,

(iii) Potential for accumulation of toxic constituents in the human body, and

(iv) Statements of expected risk to individuals or populations.

C. Emission Limits on Metals, Hydrogen Halides and Elemental Halogens

The proposed regulations included toxic metals and halogen compounds in the destruction efficiency requirement. Commenters objected on the basis that non-organic components cannot be thermally destructed and that 99.99 percent removal in the fly ash and bottom ash is not feasible.

The destruction and removal efficiency approach could be applied to metals and non-organic halogen compounds, because it considers removal of waste constituents in the emission control system and ash. Thus, metals and non-organic halogens emitted could potentially be controlled in this way and included in a destruction and removal efficiency calculation. However, the Agency elected not to apply a DRE standard to metals and non-organic halogens in the final regulation because the Agency does not have test data to indicate what specific removal levels are achievable, except in the case of hydrogen chloride emissions.

In the case of hydrogen chloride sufficient data is available to determine that air pollution control equipment can consistently remove 99% of the HCl contained in incinerator combustion gases. This determination is reflected in the interim final regulation in §264.343(c). This is further discussed in the Interim Final Incinerator Background Document.

The Agency also considered whether metals and non-organic halogens were adequately addressed through standards developed under the Clean Air Act. The only existing standard applicable to hazardous waste incinerators addresses beryllium, which is

controlled through a National Emission Standard for Hazardous Air Pollutants (NESHAP). A NESHAP standard for mercury applies to sludge incinerators but not hazardous waste incinerators. (See the discussion under II, B - other Federal Regulations).

For metals, other than beryllium, and for non-organic halogens, this proposed regulation requires that emission limits be set on a case-by-case basis by assessing the risk to human health using the same criteria established for assessing a variance to the basic DRE requirement. For metals for which EPA has developed dose response models, health effect assessments using those models could be made. For other metals or for non-organic halogens, emission assessments could be made using available health effects assessment data including TLV's or MEG's. (See IV-B - Variance to the DRE for a complete discussion of the methodology of health effect assessments.

Proposed Regulation Language

§264.343 Performance Standards

(f) After consideration of the factors listed in paragraph (g) of this Section, the Regional Administrator may, on a case-by-case basis, stipulate performance standards for metals, hydrogen halides, and elemental halogens, based on a finding that such standards are necessary to limit the emission rates of these constituents to levels which do not pose an unacceptable risk to human health and the environment.

V. Text of the Proposed Standards

§264.342 Designation of principal organic hazardous constituents and hazardous combustion by-products.

(a) Principal organic hazardous constituents (POHC's) and hazardous combustion by-products must be treated to the extent required by the performance standards specified in §264.343.

(b) (i) For each waste feed to be burned, one or more POHC's and hazardous combustion by-products will be specified from among those constituents listed in Part 261, Appendix VIII of this Chapter. This specification will be based on the degree of difficulty of incineration of the organic constituents of the waste feed and its combustion by-products, their concentration or mass, considering the results of waste analyses and trial burns or alternative data submitted with Part B of the facility's permit application. Organic constituents or by-products which represent the greatest degree of difficulty of incineration will be those most likely to be designated as POHCs or hazardous combustion by-products. Constituents are more likely to be designated as POHCs or hazardous combustion by-products if they are present in large quantities or concentrations.

(ii) Trial POHC's will be designated for performance of trial burns in accordance with the procedure specified in §122.27(b) for obtaining trial burn permits. Trial hazardous combustion by-products may be designated under the same procedures.

* * * * *

§264.343 is amended by redesignating paragraph (d) as paragraph (h) and adding new paragraphs (d), (e), (f), and (g) as follows:

§264.343 Performance standards.

* * * * *

(d) Incinerators burning hazardous waste must destroy hazardous combustion by-products designated under §264.342 so that the total mass emission rate of these by-products emitted from the stack is no more than .01% of the total mass feed rate of POHC's into the incinerator.

(e) After consideration of the factors listed in paragraph (g) of this Section, the Regional Administrator may, on a case-by-case basis, establish performance standards which are either more or less stringent than those required by paragraphs (a) and (d) of this Section based on a finding that:

(1) More stringent standards are necessary because the emission rates achieved by the application of the performance standards otherwise required by this Section may pose an unacceptable risk to human health and the environment, or

(2) Less stringent standards will achieve emission rates which do not pose an unacceptable risk to human health and the environment.

(f) After consideration of the factors listed in paragraph (g) of this Section, the Regional Administrator may, on a case-by-case basis, stipulate performance standards for metals, hydrogen halides, and elemental halogens, based on a finding that such

standards are necessary to limit the emission rates of these constituents to levels which do not pose an unacceptable risk to human health and the environment.

(g) The findings under paragraphs (e) and (f) of this Section will be made after evaluating the following data, which the Regional Administrator may require from the permit applicant:

(1) Emissions of POHC's, hazardous combustion by-products, metals, and hydrogen halides, including:

(i) Mass emission rates from the stack, and

(ii) Concentration in the gas stream exiting the stack;

(2) Air dispersion estimates for these substances, including:

(i) Meteorological data,

(ii) Description of the air dispersion models,

(iii) Assumptions underlying the air dispersion models used;

(3) Expected human and environmental exposure, including:

(i) Topographic considerations,

(ii) Population distributions,

(iii) Population activities, and

(iv) Modes, intensity and duration of exposure;

(4) Consequences of exposure, including:

(1) Dose-response curves for carcinogens,

(ii) Health effects based on human or animal studies for other toxic constituents,

(iii) Potential for accumulation of toxic constituents in the human body, and

(iv) Statements of expected risk to individuals or populations.

(h) For purposes of permit enforcement, compliance with the operating requirements specified in the permit (under §264.345) will be regarded as compliance with this Section. However, evidence that compliance with those permit conditions is insufficient to ensure compliance with the performance requirements of this Section may be "information" justifying modification; revocation, or reissuance of a permit under §122.15 of this Chapter.

* * * * *

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these chemicals are potentially human carcinogens. (Chemicals regulated as carcinogens by the Occupational Safety and Health Administration (OSHA) and the Consumer Product Safety Commission (CPSC) are also on this list but are not noted as such since they have been evaluated as being carcinogens by one of the other organizations previously mentioned). CAG evaluated the studies upon which IARC, NTP, or FDA relied and agreed with all the NTP and FDA evaluations that the chemicals presented a potential human cancer risk. The CAG agreed with most of IARC's evaluations. There are inconsistencies between the CAG and IARC evaluations for a few chemicals because the CAG considered information not available to or not otherwise used by IARC, and because there are differences in the criteria used in making the qualitative evaluations.

The list is not a comprehensive listing of all chemicals having substantial or strong evidence of carcinogenicity, chemicals which do not now appear on the list will be added. A continuing review of evaluations by organizations such IARC, NTP, FDA, OSHA, and CPSC may result in periodic revisions to the present list.

The CAG evaluates substances for possible carcinogenicity according to the procedures outlined in the Agency's Interim Guidelines for Carcinogen Risk Assessment found in Interim Procedures and Guidelines for Health Risk and Economic Impact Assessments of Suspected Carcinogens (41 Fed. Reg. 21402, May 25, 1976). These guidelines are consistent with the Interagency Regulatory

Liaison Group's Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks (Jouirnal of the National Cancer Institute 63 (1):243-268 1979, 44 Fed. Reg. 39858, July 5, 1979), and the Regulatory Council Statement on Regulation of Chemical Carcinogens (44 Fed. Reg. 760037, October 17, 1979).

Evidence concerning the carcinogenicity of chemical substances is of three types: (1) epidemiologic evidence derived from long-term bioassays on animals; and (3) supportive or suggestive evidence derived from studies of chemical-structure or from short-term mutagenicity, cell transformation or other tests that are believed to correlate with carcinogenic activity.

The CAG evaluates all available evidence on the carcinogenicity of a chemical before reaching a conclusion based on the "weight of the evidence," about the chemical's human carcinogenic potential. Conclusions about the overall weight of evidence involve a consideration of the quality and adequacy of the data and the kinds of responses induced by the suspect carcinogen. The best evidence that an agent is a human carcinogen comes from epidemiologic studies in conjunction with confirmatory animal tests. Substantial evidence is provided by animal tests that demonstrate the induction of malignant tumors in one or more species or of benign tumors that are generally recognized as early stages of malignancies. Suggestive evidence includes indirect tests of tumorigenic activity, such as mutagenicity, in vitro cell transformation, and initation-promotion skin tests in mice. Ancillary data that bear on judgments about carcinogenic

potential, e.g., evidence from systematic studies that relate chemical structure to carcinogenicity, are alos considered.

Substances were placed on the CAG list only if they had been demonstrated to induce malignant tumors in one or more animal species or to induce benign tumors that are generally recognized as early stages of malignancies, and/or if positive epidemiologic studies indicated they were carcinogenic. Although the CAG has determined that there is substantial evidence of carcinogenicity for each chemical substance on the list, the data varies to some extent with respect to the scope and quality of the studies.

No uncommonly, CAG reports are updated because new evidence becomes available. Because of this, it is important that the most recent CAG evaluation be consulted.

Some of the reports prepared by CAG are subject ot confidentiality claims. Because of these claims (primarily under the Federal Insecticide, Fungicide, and Rodenticide Act) some reports may not be released. Therefore, all requests for CAG reports and related documentation must be submitted through EPA's Freedom of Information Office (A-101), Washington, D.C. 20460, and should be marked CAG/LOC.

Benzo(b)fluoranthene (IARC)

Benzo(j)fluoranthene (IARC)@

Beryllium and Beryllium Compounds (CAG, IARC)

N,N-Bis(2-Chloroethyl)-2-Napthylamine (Chlornaphazine) (IARC)**

Cadmium and Cadmium Compounds (CAG, IARC)

Carbon Tetrachloride (CAG, IARC)

Chlorambucil (IARC)**

Chloroalkyl Ethers
- Bis(2-chloroethyl)ether (BCEE) (CAG) (IARC)@
- Bis(chloromethyl)ether (BCME) (CAG, IARC)
- Chloromethyl methyl ether (CMME), technical grade (IARC)

Chlordane (CAG, NCI)

Chlorinated Ethanes
- 1,2-Dichloroethane [Ethylene Chloride, Ethylene Dichloride (EDC)] (CAG, IARC, NCI)
- Hexachloroethane (CAG)
- 1,1,2,2-Tetrachloroethane (CAG)
- 1,1,2-Trichloroethane (CAG, NCI, IARC)@

Chlorobenzilate (CAG)

Chloroform (CAG, IARC)

Chromium Compounds, Hexavalent (CAG, IARC)

Chrysene (IARC)@

Citrus Red No. 2 (IARC)

Coal Tar and Soot (CAG, included in IARC's soots, tars, and oils designation)

Coke Oven Emissions [Polycyclic Organic Matter (POM)] (CAG)

Creosote (CAG)

Cycasin (IARC)

** Used as a drug.

@ Evaluated by IARC as not having sufficient evidence of carcinogenicity.

CHEMICALS HAVING SUBSTANTIAL EVIDENCE OF CARCINOGENICITY[a]

2-Acetylaminoflourene (See references)

Acrylonitrile (CAG, IARC)

Aflatoxins (IARC)*

Aldrin (CAG, NCI)

4-Aminobiphenyl (IARC)

Amitrole (IARC)

Aramite (IARC)

Arsenic and Arsenic Compounds (CAG, IARC)

Asbestos (CAG, IARC)

Auramine and the manufacture of Auramine (IARC)

Azaserine (IARC)**

Benz(c)acridine (IARC)@

Benz(a)anthracene (IARC)

Benzene (CAG, IARC)

Benzidine (CAG, IARC)

Benzo(a)pyrene (IARC)

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[a] This is not a comprehensive list of all chemicals having substantial evidence of carcinogenicity. Other chemicals will be added. No attempt has been made to select chemicals based upon appropriateness for regulation by EPA. The list is intended to be a basis for selection by the various program offices according to their specific needs.

* Fungal toxin, not an industrially manufactured product.

** Used as a drug.

@ Evaluated by IARC as not having sufficient evidence of carcinogenicity.

CHEMICALS HAVING EVIDENCE OF CARCINOGENICITY

In response to requests from several EPA offices, the Carcinogen Assessment Group (CAG), Office of Health and Environmental Assessment in EPA's Research and Development Office has prepared a list of chemical substances for which substantial or strong evidence exists showing that exposure to these chemicals, under certain conditions, causes cancer in human,s or can cause cancer in animal species which in turn, makes them potentially carcinogenic in humans.

The list was initially prepared in response to the needs of the OFfice of Pesticides and Toxic Substances (OPTS) to develop labeling regulations under section 6 of TSCA and the Office of Solid Waste (OSW) to develop hazardous waste regulations under section 3001 of RCRA. It is anticipated that it will serve other purposes within th Agency according to the needs of the program offices.

The sources of information used in selecting agents as candidates for the list are of two types: chemicals which the Carcinogen Assessment Group previously has evaluated and has determined pose a potential human cancer risk; and chemicals, the carcinogenicity of which the CAG reviewed because one or more of three organizations -- the International Agency for Research on Cancer (IARC), the National Cancer Institute Bioassay Program which has been reorganized into the National Toxicology Program (NTP), and the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services -- had concluded that

Cyclophosphamide (IARC)**

Daunomycin (IARC)**

DDT (Dichlorodiphenyltrichloroethane) (CAG)

Diallate (CAG) (IARC)@

Dibenz(a,h)acridine (IARC)

Dibenz(a,j)acridine (IARC)

Dibenz(a,h)anthracene (IARC)

Dibenzo(a,e)pyrene (IARC)

Dibenzo(a,h)pyrene (IARC)

Dibenzo(a,j)pyrene (IARC)

1,2-Dibromo-3-chloropropane (DBCP) (CAG, IARC, NCI)

1,2-Dibromoethane [Ethylene Bromide, Ethylene Dibromide (EDB)] (NCI, CAG, IARC)

3,3'-Dichlorobenzidine (DCB) (CAG, IARC)

Dieldrin (CAG)

Diepoxybutane (IARC)

1,2-Diethylhydrazine (IARC)

Diethylstilbestrol (DES) (IARC)**

Dihydrosafrole (IARC)

3,3'-Dimethoxybenzidine (o-Dianisidine) (IARC)

p-Dimethylaminoazobenzene (IARC)

7,12-Dimethylbenz(a)anthracene (See references)

3,3'-Dimethylbenzidine (o-Tolidine) (IARC)

Dimethylcarbamoyl Chloride (IARC)

** Used as a drug.

@ Evaluated by IARC as not having sufficient evidence of carcinogenicity.

1,1-Dimethylhydrzine (IARC)

1,2-Dimethylhydrazine (IARC)

Dimethyl Sulfate (IARC)

2,4-Dinitrotoluene (CAG, NCI)

1,4-Dioxane (NCI)

1,2-Diphenylhydrazine (CAG)

Epichlorohydrin (CAG)

Ethylene Bis Ditiocarbamate (EBDC) (CAG)

Ethyleneimine (Aziridine) (IARC)@

Ethylene Oxide (CAG, IARC)

Ethylenethiourea (CAG, IARC)

Ethyl Methanesulfonate (IARC)

Formaldehyde (CAG)

Glycidaldehyde (IARC)

Heptachlor (CAG, NCI)

Hexachlorobenzene (CAG, IARC)

Hexachlorobutadiene (CAG)

Hexachlorocyclohexane (HCH)
HCH (CAG)
HCH (CAG)
HCH (Lindane) (CAG)
Technical HCH (CAG)

Hydrazine (IARC)

Indeno(1,2,3-cd)pyrene (IARC)

Iron Dextran (IARC)**@

** Used as a drug.

@ Evaluated by IARC as not having sufficient evidence of carcinogenicity.

Isosafrole (IARC)

Kepone (Chlordecone) (CAG, NCI)

Lasiocarpine (IARC, NCI)

Melphalan (IARC)**

Methapyrilene (FDA)**

3-Methylchoanthrene (See references)

4,4'-Methylenebis(2-Chloroaniline) (MOCA) (IARC)

Methyl Iodide (CAG, IARC)

Methyl Methanesulfonate (IARC)

N-Methyl-N'-nitro-N-nitrosoguanidine (IARC)

Methylthiouracil (IARC)**

Mustard Gas (IARC)

1-Naphthylamine, technical grade (CAG)

2-Naphthylamine (IARC)

Nickel and Nickel Compounds (CAG, IARC)

Nitrogen Mustard and its hydrochloride (IARC)

Nitrogen Mustard N-oxide and its hydrochloride (IARC)

5-Nitro-o-toluidine (NCI)

4-Nitroquinoline-1-oxide (See references)

Nitrosamines
- N-Nitrosodiethanolamine (IARC)
- N-Nitrosodiethylamine (DENA) (CAG, IARC)
- N-Nitrosodimethylamine (DMNA) (CAG, IARC)
- N-Nitrosodi-n-butylamine (IARC)
- N-Nitrosomethylethylamine (IARC)
- N-Nitrosodi-n-propylamine (IARC)
- N-Nitrosomethylethylamine (IARC)
- N-Nitrosomethylvinylamine (IARC)

** Used as a drug.
@ Evaluated by IARC as not having sufficient evidence of carcinogenicity.

N-Nitroso-N-Ethylurea (NEU) (CAG, IARC)
N-Nitroso-N-Methylurea (NMU) (CAG, IARC)
N-Nitroso-N-methylurethane (IARC)
N-Nitrosomorpholine (IARC)
N-Nitrosonornicotine (IARC)
N-Nitrosopiperidine (IARC)
N-Nitrosopyrrolidine (IARC)
N-Nitrososarcosine (IARC)

Pentachloronitrobenzene (PCNB) (CAG)

Phenacetin (IARC)**

Polychlorinated Biphynyls (PCBs) (CAG, IARC)

Pronamide (CAG)

1,3-Propane Sulton (IARC)

3-Propiolactone (IARC)

Propylthiouracil (IARC)**

Reserpine (NCI)**

Saccharin (FDA)***

Safrole (CAG, IARC)***

Selenium Sulfide (NCI)

Streptozotocin (IARC)**

2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) (CAG)

Tetrachloroethylene (Perchloroethylene) (CAG, NCI)

Thioacetamide (IARC)

Thiourea (IARC)

o-Toluidine Hydrochloride (NCI)

Toxaphene (CAG, IARC, NCI)

Trichloroethylene (CAG, NCI)

** Used as a drug.

*** Used as a food.

2,4,5-Trichlorophenol (NCI)

Tris(1-aziridinyl)phosphine sulfide (thio-TEPA) (IARC, NCI)**

Tris(2,3-dibromopropyl)phosphate (IARC, NCI)

Trypan Blue, commercial grade (IARC)

Uracil Mustard (IARC)**

Urethane (IARC) (Ethyl carbamate; ethyl ester of carbamic acid)

Vinyl Chloride (CAG, IARC)

Vinylidene Chloride (CAG)

** Used as a drug.